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Persistent Organic Pollutants Review Committee
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Item 5 (a) of the provisional agenda*

Technical work: consideration of a draft risk management evaluation on decabromodiphenyl ether (commercial mixture, c-decaBDE)

Draft risk management evaluation: decabromodiphenyl ether (commercial mixture, c-decaBDE)

Note by the Secretariat

I. Introduction

1. At its tenth meeting, the Persistent Organic Pollutants Review Committee adopted decision POPRC-10/2 on decabromodiphenyl ether (commercial mixture, c-decaBDE) (UNEP/POPS/POPRC.10/10, annex I). By paragraph 3 of that decision, the Committee decided to establish an intersessional working group to prepare a risk management evaluation that included an analysis of possible control measures for decabromodiphenyl ether (commercial mixture, c-decaBDE) in accordance with Annex F to the Stockholm Convention on Persistent Organic Pollutants.

2. In accordance with decision POPRC-10/2 and the workplan for the preparation of a draft risk management evaluation adopted by the Committee (UNEP/POPS/POPRC.10/10, annex III), the intersessional working group has prepared a draft risk management evaluation, which is set out in the annex to the present note without formal editing. A supporting document and a compilation of comments and responses relating to the draft risk management evaluation are set out in documents UNEP/POPS/POPRC.11/INF/6 and UNEP/POPS/POPRC.11/INF/7, respectively.

II. Proposed action

3. The Committee may wish:

(a) To adopt, with any amendments, the draft risk management evaluation set out in the annex to the present note;

(b) To decide, in accordance with paragraph 9 of Article 8 of the Convention, on the basis of the risk profile adopted at its tenth meeting (UNEP/POPS/POPRC.10/10/Add.2) and the risk management evaluation, whether decabromodiphenyl ether (commercial mixture, c-decaBDE) should be recommended for consideration by the Conference of the Parties for listing in Annexes A, B and/or C to the Convention.

* UNEP/POPS/POPRC.11/1.

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Annex

DECABROMODIPHENYL ETHER

(commercial mixture, c-decaBDE)

DRAFT RISK MANAGEMENT EVALUATION

Prepared by the intersessional working group on decabromodiphenyl ether
Persistent Organic Pollutants Review Committee

July 2015

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Executive summary

1. In 2013, Norway submitted a proposal to list commercial decabromodiphenyl ether (c-decaBDE) as a persistent organic pollutant under the Stockholm Convention. In 2014, at the 10th meeting of the POPs Review Committee, it was decided thatBDE-209,themain constituent of c-decaBDE is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted. An ad hoc working group was established to prepare a risk management evaluation for c-decaBDE, in accordance with Annex F of the Convention, for consideration by POPs Review Committee at its 11th meeting in October 2015.

2. C-decaBDE is an intentionally produced chemical consisting of the fully brominated decaBDE congener or BDE-209 (≥90-97%), with small amounts of nona- and octa-bromodiphenyl ether. C-decaBDE has been under investigation for its potential health and environmental impacts for more than a decade and has been subject to restrictions and voluntary risk management actions in some countries and regions, as well as by some companies. Production of c-decaBDE but is still ongoing in a few countries globally.

3. C-decaBDE is an additive flame retardant that has a variety of applications including in plastics, textiles, adhesives, sealants, coatings and inks. C-decaBDE containing plastics are used in electrical and electronic equipment, wires and cables, pipes and carpets. In textiles, c-decaBDE is mainly used in upholstery, window blinds, curtains and mattresses for public and domestic buildings, and in the transportation sector. The amount of c-decaBDE used in plastics and textiles globally varies but up to about 90% of c-decaBDE ends up in plastic and electronics while the remaining ends up in coated textiles, upholstered furniture and mattresses.

4. Emissions of c-decaBDE to the environment occur at all its life cycle stages, but are assumed to be highest during service life and in the waste phase. Monitoring data shows that c-decaBDE levels are generally highest near wastewater discharges and in areas around electronic waste and recycling plants. The average service life for electric and electronic equipment is about 10 years hence c-decaBDE will continue to be released to the environment through articles in use for years to come. The most efficient control measure to reduce the releases of c-decaBDE and its main constituent BDE-209, would be to list BDE-209 (c-decaBDE) in Annex A of the Convention without specific exemptions. Furthermore, efficient control measures for the handling of waste containing c-decaBDE will also be essential. Due to the historical- and present use of c-decaBDE as a flame retardant, a large number of products in use will become waste in the future. Controlled incineration of waste containing c-decaBDE at high temperatures is one way of destruction, with systems to remove possible brominated furan/dioxin compounds produced in the process, along with continuous monitoring and strict compliance with Convention BAT/BEP guidelines and environmentally sound treatment of fly ashes.

5. According to Article 6 of the Convention, waste shall be disposed of in such a way that the POP content is destroyed or irreversibly transformed so that it does not exhibit the characteristics of POPs, or otherwise disposed of in an environmentally sound manner when destruction or irreversible transformation does not represent the environmentally preferable option or the POP content is low.For this reason, recycling of material containing c-decaBDE above the low POP content limit value is not recommended and should be avoided. Recently, BDE-209 has been detected in a number of articles, made from recycled material, including articles in contact with food. This indicates that it is difficult to control the content of c-decaBDE in plastic material destined for recycling and that recycling may contribute to human exposure to c-decaBDE. Monitoring data also shows that recycling contributes to significant environmental pollution and health risks for local populations, particularly in developing countries where recycling occurs in the informal sector.Technical solutions are available in the waste sector to achieve more sustainable wastemanagement e.g. by sorting out components containing hazardous chemicals. Atpresent, recycling of c-decaBDE containing plastics and textiles is not known to occur to a great extent and available information suggests that the socioeconomic impact of not recycling c-decaBDE may be limited.

6. According to the Annex F information submitted by Parties and Observers, no critical uses of c-decaBDE have been identified. A later stage some industry Observers suggested a possible need for an exemption, for service and replacement of parts as well as for manufacture of new vehicles and aircrafts under existing type certificates, in the transportation sector. However, a number of chemical alternatives are already on the market for the substitution of c-decaBDE in plastics and textiles. Furthermore, non-chemical alternatives and technical solutions such as non-flammable materials and physical barriers, respectively, are also available. Annex F information and other available information indicates that textile-, furniture- and electronics markets are in transition away from the use of c-decaBDE and that substitutions have been performed or are in progress for most, if not all, known

applications. In addition, a small number of Parties have suggested a possible recycling exemption for materials containing c-decaBDE.

7. A positive impact on human health and the environment can be expected from a global reduction or elimination of c-decaBDE. BDE-209, the main constituent of c-decaBDE, and its degradation products is widely detected in the indoor and outdoor environments and is found in some organisms at levels close to or at reported effect concentrations for developmental-, neurotoxic-, and endocrine disruptive effects.

1. Introduction

8. On 13 May 2013, Norway as a Party to the Stockholm Convention, submitted a proposal to list decabromodiphenyl ether (commercial mixture, c-decaBDE) in Annexes A, B and/or C to the Convention. The proposal (UNEP/POPS/POPRC.9/2) was submitted in accordance with Article 8 of the Convention and was reviewed by the POPs Review Committee (POPRC) at its ninth meeting in October 2013, where the Committee agreed that the criteria in Annex D were met. At its tenth meeting in October 2014, the Committee evaluated the draft risk profile for c-decaBDE (UNEP/POPS/POPRC.10/10/Add.2) in accordance with Annex E, adopted this (UNEP/POPS/POPRC.10/10) and decided to establish an intersessional working group to prepare a risk management evaluation for the substance (Decision POPRC-10/2).

9. In the present document, the abbreviation c-decaBDE is used for technical or commercial decaBDE products. Decabromodiphenyl ether (BDE-209) refers to the single fully brominated polybromiated diphenylether (PBDE), which elsewhere sometimes is denoted as decaBDE.

1.1 Chemical identity of the proposed substance

10. The risk management evaluation concerns c-decaBDE and its main component, BDE-209. C-decaBDE is a commercial PBDE formulation that is widely used as an additive flame retardant in textiles and plastics, additional uses are in adhesives and in coatings and inks (ECHA 2013b). C-decaBDE consist predominantly of the congener BDE-209 (≥97%), with low levels of other PBDE congeners such as nonabromodiphenyl ether (0.3-3%) and octabromodiphenyl ether (0-0.04%). Chen et al. (2007) reported that the octaBDE and nonaBDE content of two c-decaBDE products from China was in the range 8.2 to 10.4% suggesting that a higher degree of impurities may be found in some commercial mixtures. Historically a range of 77.4-98% of BDE-209, and smaller amounts of the congeners of nonaBDE (0.3-21.8%) and octaBDE (0-0.85%) have been reported (ECHA, 2012a; U.S. EPA, 2008; RPA, 2014). Total tri-, tetra-, penta-, hexa- and heptaBDEs are typically present at concentrations below 0.0039% w/w (ECB 2002; ECHA 2012a). Trace amounts of other compounds, thought to be hydroxybrominated diphenyl compounds can also be present as impurities. In addition, polybrominated dibenzo-p-dioxins and polybrominated dibenzofurans (PBDD/Fs) have been reported as impurities in some c-decaBDE products (Renet al., 2011).

11. Chemical data on the main component of c-decaBDE, BDE-209, are presented in Figure 1 and in Tables 1 and 2 below (ECHA, 2012a). According to available information, c-decaBDE is currently available from several producers and suppliers globally (Ren et al., 2013; RPA, 2014) and is marketed under different trade names (Table 1).

Figure 1. Structural formula

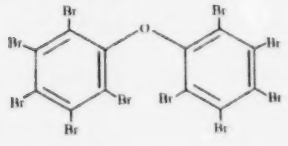

Table 1. Chemical identity of c-decaBDE and its main constituent BDE-209

CAS number:	1163-19-5[1]
CAS name:	Benzene, 1,1'-oxybis[2,3,4,5,6-pentabromo-]
IUPAC name:	2,3,4,5,6-Pentabromo-1-(2,3,4,5,6-pentabromophenoxy)benzene
EC number:	214-604-9
EC name:	Bis(pentabromophenyl) ether
Molecular formula:	$C_{12}Br_{10}O$
Molecular weight:	959.2 g/mole
Synonyms:	decabromodiphenyl ether, decabromodiphenyl oxide, bis(pentabromophenyl) oxide, decabromo biphenyl oxide, decabromo phenoxybenzene, benzene 1,1' oxybis-, decabromo derivative, decaBDE, DBDPE[2], DBBE, DBBO, DBDPO
Trade names:	DE-83R, DE-83, Bromkal 82-ODE, Bromkal 70-5, Saytex 102 E, FR1210, Flamecut 110R. FR-300-BA, which was produced in the 1970s, is no longer commercially available (ECA, 2010).

[1]In the past CAS no. 109945-70-2, 145538-74-5 and 1201677-32-8were also used. These CAS no. have now formally been deleted, but may still be in practical use by some suppliers and manufacturers.
[2]DBDPE is also used as an abbreviation for Decabromodiphenyl Ethane CAS no. 84852-53-9.

Table 2. Overview of relevant physicochemical properties of c-decaBDE and its main constituent BDE-209

Property	Value	Reference
Physical state at 20°C and 101.3 kPa	Fine, white to off-white crystalline powder	ECB (2002)
Melting/freezing point	300-310°C	Dead Sea Bromine Group (1993), cited in ECB (2002)
Boiling point	Decomposes at >320°C	Dead Sea Bromine Group (1993), cited in ECB (2002)
Vapour pressure	4.63×10^{-6} Pa at 21°C	Wildlife International Ltd (1997), cited in ECB (2002)
Water solubility	<0.1 µg/L at 25°C (column elution method)	Stenzel and Markley (1997), cited in ECB (2002)
n-Octanol/water partition coefficient, K_{ow} (log value)	6.27 (measured – generator column method) 9.97 (estimated using an HPLC method)	MacGregor and Nixon (1997), Watanabe and Tatsukawa (1990), respectively, cited in ECB (2002)
Octanol-air partition coefficient K_{oa} (log value)	13.1	Kelly et al. (2007)

1.2 Conclusions of the Review Committee, Annex E information

12. At its 10th meeting the Committee concluded that, "C-decaBDE is a synthetic substance with no known natural occurrence that is used as a flame retardant in many applications worldwide. Releases of c-decaBDE to the environment are continuing in all regions investigated. BDE-209 (or decaBDE), the main constituent of c-decaBDE is persistent in the environment and bioaccumulates and biomagnifies in several species of fish, birds and mammals as well as in food webs. There is evidence for adverse effects to critical endpoints including reproduction, survival, nerve- and endocrine systems. C-decaBDE is also degraded to lower brominated PBDEs, with known PBT/vPvB and POP properties. Lower brominated congeners contribute in the outcome of BDE-209 toxicity. Due to debromination and historical reservoirs of c-penta- and c-octaBDE congeners in the environment, organisms are exposed to a complex mixture of PBDEs that in combination pose a higher risk than BDE-209 alone. Measured BDE-209 levels in some species of biota, including higher trophic levels such as birds and mammals in source and remote regions are close to reported effect concentrations and indicate that BDE-209 together with other PBDEs pose a significant concern for human health and the environment. C-decaBDE with its main constituent BDE-209 is likely, therefore, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted".

13. The Committee also decided to establish an ad hoc working group to prepare a risk management evaluation that includes an analysis of possible control measures for decaBDE in accordance with Annex F of the Convention for consideration at its next meeting.

1.3 Data sources

14. The risk management evaluation was developed using information contained in the risk profile (UNEP/POPS/POPRC.10/10/Add.2) and Annex F information submitted by Parties and other stakeholders including non-governmental organizations as well as industry. Eight Parties and Observers submitted information: Australia, Canada, China, Japan, Mali, The Netherlands, Serbia, and USA. Four non-governmental Observers submitted information: European Automobile Manufacturers Association (ACEA), Bromine Science and Environmental Forum (BSEF), ICL-Industrial Products, Paxymer AB as well as the International POPs Elimination Network (IPEN). All Annex F submissions are available on the Convention website (www.pops.int).

15. Scientific literature obtained from scientific databases such as ISI Web of Science and PubMed was included as well as "grey" literature such as government reports, risk- and hazard assessments, industry fact sheets etc.

1.4 Status of the chemical under international conventions

16. In 1992, brominated flame retardants (BFRs) were given priority in the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) action plan. In 1998 c-decaBDE along with the other PBDEs was included in the list of "Chemicals for Priority Action" as well in the Joint Assessment and Monitoring Programme in OSPAR. OSPAR has promoted actions in the EU on risk-reduction strategies for c-decaBDE and electronic waste legislation.

17. In 1995, OECD Member countries agreed to oversee a voluntary industry commitment (VIC) by some of the global manufacturers of BFRs, among them c-decaBDE, to take certain risk management actions. The VIC was implemented in the United States, Europe and Japan. C-decaBDE production has since ceased in Europe and continues to be phased out in the United States. In Japan, compliance with the VIC is on-going. In parallel to this work, OECD conducted an investigation of the waste management practices in member countries with respect to products containing BFRs. The results of this investigation are documented in the Report on the Incineration of Products Containing Brominated Flame Retardants (OECD 1998). A Screening Information Data Sets (SIDS) Initial Assessment Profile (SIAP) on BDE-209 was prepared under the Environment, Health and Safety (EHS) Programme of the OECD and adopted by SIAM 16 and later endorsed by the OECD Joint Meeting in 2003. The Hazard/Risk Information Sheets for c-decaBDE and four other BFRs were updated in 2005, 2008 and 2009 (OECD 2014). PBDEs, including BDE-209, are listed as chemicals of concern in the WHO/UNEP "State of the science of endocrine disrupting chemicals" (WHO/UNEP 2013).

1.5 Any national or regional control actions taken

18. C-decaBDE has been under scrutiny for its potential health and environmental impacts for more than a decade. Steps to restrict the use of c-decaBDE have been taken in some countries and regions, as well as by some of the major electronic companies (for an overview: UNEP/POPS/POPRC.9/2, Ren et al., 2011).

19. In Europe, regulations on c-decaBDE are in place in the EU and Norway. With the European Restriction of Hazardous Substances Directive (RoHS), the use of PBDEs, including c-decaBDE was banned in electronic and electrical equipment (EEE) in the EU at concentrations above 0.1% by weight of homogeneous material. Although this legislation came into force in February 2008, medical equipment was initially exempt. In June 2011 however, this exemption was removed and medical devices fall within the scope of RoHS with effect from 22 July 2014.In 2012 c-decaBDE was identified as a PBT/vPvB (persistent, bioaccumulative and toxic/ very persistent, very bioaccumulative) substance in the EU and included in the Candidate List of substances of very high concern (SVHCs) under the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH).The EU are now considering a proposal to restrict the manufacture, uses and placing on the market of c-decaBDE as a substance and as a constituent of other substances, or in mixtures, if the concentration is equal or greater than 0.1% by weight. Articles containing c-decaBDE in concentrations greater than 0.1% by weight are also proposed to be restricted. However, derogations are suggested for articles on the second hand market, for EEE covered by the existing ban for these products, and for articles used in the aviation sector such as in production, maintenance, repair or modification of any aircraft or component eligible for installation produced in accordance with a type certificate or restricted type certificate (ECHA 2014a). In Norway production, import, export, placing

on the market and use of c-decaBDE at concentrations 0.1 % or more as a substance and in preparations and in articles are prohibited. The ban, which entered into force in 2008, includes all uses except the use of c-decaBDE in means of transportation. In addition, c-decaBDE is included in the Waste regulations which prescribes that waste containing c-decaBDE at or above 0.25% must be handled as hazardous waste.

20. In North America, the first restriction was adopted in Canada in 2008 with a ban on manufacture of PBDEs, including c-decaBDE, under the PBDE Regulations (Environment Canada 2008). In August 2010, Environment Canada and Health Canada published a Final Revised Risk Management Strategy for PBDEs which reiterated the objective of reducing the concentration of PBDEs in the Canadian environment to the lowest level possible. This resulted in agreement with three large worldwide producers of c-decaBDE to voluntarily phase-out the export of c-decaBDE to Canada. The voluntary agreement included a phase-out of c-decaBDE exports and sales for EEE by the end of 2010, for transportation and military uses by the end of 2013 and for all other uses by the end of 2012 (Environment Canada 2010). On April 4 2015, Canada published proposed regulations to prohibit the use, sale, offer for sale and import of tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE and products containing them (e.g. resins, mixtures, polymers). The regulatory proposal excludes manufactured items. Canada has consulted on its plan to regulate PBDEs in products other than in mixtures, polymers and resins: http://www.chemicalsubstanceschimiques.gc.ca/fact-fait/glance-bref/pbde-eng.php.A voluntary phase out is also ongoing in the U.S. On December 17, 2009, as a result of negotiations with the United States Environment Protection Agency(U.S. EPA), the two U.S. producers of c-decaBDE and the largest U.S. importer announced commitments to voluntary phase out c-decaBDE in the U.S. (Annex F USA). The commitments consisted of reductions in the domestic manufacture, import, and sales of c-decaBDE starting in 2010. The U.S. EPA then encouraged other importers of c-decaBDE to join this initiative. As part of this encouragement, the U.S. EPA developed a Design for the Environment and Green Chemistry alternatives assessment for c-decaBDE to aid users in selecting suitable alternatives. In addition, the U.S. EPA proposed an update to the PBDE Significant New User Rule (SNUR) and simultaneously proposed a Toxic Substances Control Act (TSCA) section 4 test rule for c-pentaBDE, c-octaBDE, and c-decaBDE. As proposed, the test rule would require development of information necessary to determine the effects of manufacturing, processing, or other activities involving these c-PBDEs on human health or the environment. In the proposal, the U.S. EPA stated its intention to promulgate the SNUR for anyone who intends to manufacture (including import) or process any of the chemicals for an activity that is designated as a significant new use, and to promulgate a TSCA section 4 test rule if it determines that manufacture (including import) or processing of c-PBDEs, including in articles, has not ceased by December 31, 2013.In addition, the U.S. EPA helped establish the Furniture Flame Retardancy Partnership (as part of the U.S. EPA's Design for the Environment Program). This is a joint venture between the Furniture Industry, Chemical Manufacturers, Environmental Groups, and the U.S. EPA to better understand fire safety options for the furniture industry. This type of group has helped the textile and foam industries to quickly transition away from BFRs (U.S. EPA, 2014b). Additionally, in the U.S., several states have also imposed restrictions on the manufacture and/or use of c-decaBDE in certain applications, including in mattresses, mattress pads and other bedding products, seating, furniture and electronic products (U.S. EPA, 2014a). Up-to-date information on state regulations can be found in the U.S. State-level Chemicals Policy Database, see http://www.chemicalspolicy.org/chemicalspolicy.us.state.database.php(LSCP 2015).

21. In Asia, restrictions have been adopted in China, India and Korea. In the revision of the Chinese RoHS legislation (Administrative Measure on the Control of Pollution Caused by Electronic Information Products) a restriction on the use of c-decaBDE in EEE was adopted (BSEF 2012). According to Annex F information from China, PBDEs are not allowed in EEE at concentrations above 0.1% by weight. In addition, labelling is required when PBDEs are used in scanners, vacuum cleaners, video cameras, printers, fax machines, multifunction devices, digital disc players, voice recorders, colour television broadcasting receivers, mobile hard disk drives, cameras, ink for ink jet printing, leather and synthetic leather, digital stencil duplicator, microcomputers and displays, household electric washing machines, room air conditioners, furniture, refrigerators, ballasts for tubular fluorescent lamps and household microwave ovens. E-waste must be handled in accordance with the legislation on the Waste of Electrical and Electronic Equipment (Jinhui et al., 2015; BSEF, 2015a). Furthermore, it has been reported that in China e-waste containing PBDE FRs should be separated out and disposed of as hazardous waste (Jinhui et al. 2015). Korea implemented a law in 2008, which covers end-of-life and restrictions on electronic products and vehicles. Exemptions, limit values and restricted substances are the same as the EU RoHS Directive. C-decaBDE is exempted from the list of hazardous substances in polymeric applications under the Recycling of Resource in Electronic Equipment and Automobiles' Regulation (BSEF 2012). In India, the e-waste (management and handling) Rules came into effect in May 2012. The chapter on the Restriction of hazardous

substances under the e-waste rules restricts the use of PBDEs in EEE with a threshold limit of 0.1% (BSEF, 2012, 2015b). In Japan, under the Chemical Substances Control Law, the annual production or import volumes of BDE-209 have to be reported along with shipment volumes (Annex F, Japan).

22. In addition to the above measures taken by countries, initiatives to voluntarily phase-out c-decaBDE have been taken by industry. Many electronics firms have already eliminated or committed to eliminating c-decaBDE in accordance with the EU RoHS, including Philips, Electrolux, Sony, Dell, Intel, Sharp, Apple and Hewlett Packard (Ren et al., 2011). Other industrial stakeholders have also implemented/ launched voluntary initiatives. In 1986, the German Chemicals Industry Association (VCI) voluntarily agreed to discontinue the use of c-decaBDE because of concerns about the potential for brominated dioxins/furans emissions from incomplete combustion (ECHA, 2012c). The European Flame Retardant Association (EFRA) together with the industry's global organisation, the Bromine Science and Environmental Forum (BSEF), has moreover launched a voluntary initiative whereby member companies aims to manage, monitor and minimize industrial emissions of high production volume BFRs, including decaBDE through partnership with the supply chain (VECAP, 2012). This program, called the Voluntary Emissions Control Action Program (VECAP) started in Europe in 2004 but has later also been introduced in North America and in Japan. The member companies of the BSEF moreover agreed with the U.S. EPA and Canadian authorities to voluntarily phase out production, import and sales of c-decaBDE in the United States and Canada as of the end of 2013.Furthermore, large global furniture producers, such as Ikea, have phased-out the use PBDEs including c-decaBDE and several mattress producers globally now offer PBDE-free mattresses (see e.g. http://mattresszine.com/mattress-news/pbde-free-manufacturer-product-list/).Ikea, along with many other companies, is actively promoting PBDE-free furniture.

2. Summary information relevant to the risk management evaluation

23. As discussed in the risk profile, c-decaBDE is produced in high quantities worldwide (UNEP/POPS/POPRC.10/10/Add.2, UNEP/POPS/POPRC.10/INF/6). In the past, c-decaBDE constituted75-80% of the world total production of PBDEs (KemI, 2005; RPA, 2014) and thetotal global production of c-decaBDE in the period 1970-2005 was between 1.1-1.25 million tonnes, similar to the scale of production of PCBs (Breivik, 2002).

24. The many uses and applications of c-decaBDE is reviewed in the risk profile (UNEP/POPS/POPRC.10/10/Add.2, see also Table 1, UNEP/POPS/POPRC.11/INF/6) but can be roughly divided into two main categories – in plastics polymers and in textiles. As discussed in detail in the risk profile the c-decaBDE use within these application vary between different countries and regions. Further as described in the risk profile, emissions of c-decaBDE to the environment occurs at all its life cycle stages; during production, formulation and other first- and second-line uses at industrial/professional sites, as well as during service life of articles, their disposal as waste and during recycling operations (UNEP/POPS/POPRC.10/10/Add.2 and references within). The release and distribution of c-decaBDE to the environment via these routes is confirmed by monitoring data (UNEP/POPS/POPRC.10/INF/6), and are likely to occur over a long time-frame.

25. A number of emission assessments have been performed based on modelling (UK EA, 2009; RPA, 2014; ECHA, 2014a; Earnshaw et al., 2013). The assessments collectively indicate that emissions of c-decaBDE during service life and upon disposal of products (as waste) are the most important sources of release, and are in line with reported environmental monitoring data (UNEP/POPS/POPRC.10/10/Add.2).

26. Control measures should be considered for all the above described sources of exposure and releases including production, use and in the waste management phase.

2.1 Identification of possible control measures

27. The objective of the Stockholm Convention (Article 1) is to protect human health and the environment from POPs. This may be achieved by listing c-decaBDE in Annex A, B and/ or C in the Convention, possibly accompanied with exemptions for certain uses and/or acceptable purposes. Given that BDE-209 the main constituent of c-decaBDE, is likely as a result of its long range environmental transport to lead to significant adverse human health and environmental effects such that global action is warranted (UNEP/POPS/POPRC.10/10/Add.2, UNEP/POPS/POPRC.10/10), and mindful of the precautionary approach set forth in Article 1 of the Convention, the aim of any risk reduction strategy for c-decaBDE should be to as far as possible reduce and eliminate emissions and releases of c-decaBDE. The most effective control measure would be to list c-decaBDE in Annex A of the Convention with no exemptions for production and use.

28. If c-decaBDE is listed in the Convention, the provisions of Article 6(1)(d)(ii) have to be fulfilled. This means that waste shall be disposed of in such a way that the POP content is destroyed or irreversibly transformed so that it does not exhibit the characteristics of POPs, or otherwise disposed of in an environmentally sound manner when destruction or irreversible transformation does not represent the environmentally preferable option or the POP content is low. Parties should also consider emission reduction measures and the use of best available techniques and best environmental practices (BAT/BEP) in the waste management phase. In addition, Parties shall endeavour to develop appropriate strategies for identifying sites contaminated with c-decaBDE. If contaminated sites are identified and remediation is undertaken, it shall be performed in an environmentally sound manner.

29. In the event that the Conference of the Parties agrees on specific exemptions and/or acceptable purposes, emission reduction measures and the use of BAT/BEP during production and manufacture should also be considered. Additional measures linked to potential exemptions and/or acceptable purposes could include a requirement on proper and informative labelling or other means of identification of c-decaBDE-containing products similar to what was agreed upon when listing HBCD (SC-6/13).Labelling of containers with POPs waste may be a necessary measure in order to effectively manage the products upon becoming wastes (Basel Convention, 2015b).

30. Though most of the Parties and Observers support listing c-decaBDE in Annex A without exemptions, some Parties and Observers have also identified the need for a possible exemption for recycling.Furthermore, some transportation industry associations have identified a need for exemptions for the use of c-decaBDE in the production, maintenance, repair,and modifications of aircrafts and vehicles under existing type certificates. The need for these exemptions has also been proposed under the ongoing restriction process in the EU where an exemption for the automotive industry is not supported due to, amongst others, potentially high emissions from this use and because the reason for providing an exemption is mainly economic.The Canadian Vehicle Manufacturer's Association raises a concern for a ban on production and use of c-decaBDE due to the requirement to provide service and replacement parts for vehicles already on the market. Further, according to The Boeing Company and the Aerospace and Defence industries Association of Europe, c-decaBDE is largely substituted in newer products, but presently not for all uses. In addition, the aviation and aerospace industry indicated a need for use of c-decaBDE as a FR in components and spare parts in airplanes including a range of polymer, textile and electrical items. With regards to the request for an exemption for use in vehicles it should be noted that for most of the automotive plastics, the fire safety requirements in Europe are not very strict, and therefore most plastics are not flame retarded. Moreover, most car manufacturers follow the safety standard of the European New Car Assessment Program, Euro NCAP, which is stricter than the standard required by law (IVM, 2013).

31. C-decaBDE phase-out could include FR substitution, resin/material substitution and product redesign as well as re-evaluation of fire-safety requirements. As further discussed in chapter 2.3 of this document, alternatives, although with different hazard profiles, to all uses of c-decaBDE are available and accessible (ECHA 2014a; U.S. EPA, 2014a).Moreover, for a wide range of the applications where c-decaBDE is used other FRs have already replaced c-decaBDE (Kemi 2005). In addition, some of the exemptions requested by the transportation industry may not necessitate an exemption under the Convention because they concern products and articles that have already been placed on the market. According to the text of the Convention listing of chemicals in Annex A or B does not apply to"quantities of a chemical occurring as constituents of articles manufactured or already in use before or on the date of entry into force of the relevant obligation with respect to that chemical, shall not be considered as listed in this annex". This suggests that a complete phase-out of c-decaBDE from all uses is possible and that exemptions for production and use to a large extent are not critical.

2.2 Efficacy and efficiency of possible control measures in meeting risk reduction goals

32. In order to reduce c-decaBDE emissions control measures at all life cycle stages need to be in place.

33. Although waste is recognized as an important source to c -decaBDE emissions, it was recently reported that articles in service life are the largest source of c-decaBDE emissions (RPA, 2014; ECHA, 2014a). For articles, various possible risk management options could be considered. However, the control measure that most effectively will abate global emissions is to globally ban the production and use of c-decaBDE in articles and avoid recycling of products containing c-decaBDE. According to information presented in Section 2.3, the phase-out of c-decaBDE in new products is technically feasible and may be accomplished within a short time-frame given that alternatives for all known uses are available and accessible. Articles in use will however contribute to environmental emissions for some time after a global ban or restriction on use has entered into force. Exactly how long products

will continue to be a source of c-decaBDE emissions is difficult to predict. The estimated service life for products containing c-decaBDE varies between products (i.e. EEE or upholstery) and between global regions. Moreover, c-decaBDE is used in such a wide range of products that estimating service lifetimes for each type of product is challenging. An average of 10 year service life was used in European emission estimates (Earnshaw et al., 2013). According to Buekens and Yang (2014) EEE have an average service life of 3-12 years globally, with larger appliances having longer service life. In China, the estimated service life is 10-16 years for most EEE products except computers that are reported to have a service life of no more than 4-6 years (Yuan, 2015). In some developing countries, service lives of different c-decaBDE products may be even longer.

34. In addition to releases from articles during service life, releases from products and articles upon becoming waste are also of significant concern (Earnshaw et al., 2013; Tsydenova and Bengtsson 2011; UK EA 2009). Following a listing of c-decaBDE in the Stockholm Convention a concentration level for low POP content would typically be established in cooperation with the Basel Convention, which also typically will be tasked with determining the methods that constitutes environmentally sound disposal.Introducing waste management measures, including measures for products and articles upon becoming waste, in accordance with Article 6 of the Convention, would ensure that wastes containing c-decaBDE at concentrations above the low POP content are disposed in an effective and efficient way such that their POPs content is destroyed or otherwise disposed in an environmentally sound manner. These measures would also address proper waste handling, collection, transportation and storage and ensure that emissions and related exposures to c-decaBDE from waste are minimized. Establishment of the low POP value and the guidelines developed by the Basel Convention will help Parties to dispose of waste containing c-decaBDE in an environmentally sound manner (UNEP/CHW.12/INF/9).

35. C-decaBDE is expected to be present in plastics and textiles in several waste streams such as "End of Life Vehicles" (ELV), e-waste, textile- and mixed waste. Information on c-decaBDE levels in these waste streams is limited. For the global measures to be efficient, proper waste handling could require identifying BDE-209 containing materials to facilitate destruction of the POP content in the waste (UNEP/CHW.12/INF/9).For collected waste streams, materials containing c-decaBDE could be sorted out, either manually or by use of automated sorting and separation systems. Automated sorting will not always be feasible as c-decaBDE containing materials cannot be readily identified without the use of advanced technical equipment or because the c-decaBDE containing waste is mixed with other materials which makes the sorting more technically challenging. However, establishing an inventory of c-decaBDE containing wastes may assist Parties as well as the waste industry in identifying waste fractions that may contain c-decaBDE, thereby allowing proper, although more crude sorting of the waste also by manual methods. According to newly published studies by the Nordic Council of Ministers, e-waste treatment processes with significant low-technology elements, including manual disassembly and separation of e-waste, can currently achieve significantly better plastic recycling than highly mechanised and automated alternatives. Lower-technology approaches carry relatively higher costs and may otherwise appear unattractive in a sector where technological advance seems vital. However, e-waste plastics are especially challenging to recycle and dependent on high-quality processes (NCM, 2015a).

36. One of the more common technologies for sorting out waste containing halogens is x-ray fluorescence (XRF) spectrometry, which simply identifies the presence of bromine, rather than specific compounds such as BDE-209. The method is compatible with both manual and automated sorting of wastes. Waste can also be sorted using other optical methods. Similar to the XRF technology these technologies are compatible with automatisation and separates wastes based on colour, shape or polymer type. While bichromatic colour sorters can separate by colour or shape, near infrared (NIR) cameras can recognize different polymers. However, unless detectable black colorants are used automatic optical sorting machines cannot detect black plastic waste (NCM, 2015b). Furthermore, density (sink-float) technologies are reported as being viable for some of the necessary separations of plastics waste. This technologyiscommercially available globally and allows separation of FR containing plastics from non-FR plastics and different types of plastics from each other, but does not distinguish between different FRs (Peeters et al., 2014, NCM, 2014a and referenced therein, Stockholm Convention, 2012a).When it comes to sorting plastics from WEEE, NIR technology as well as various flotation methods may be used to achieve maximal purity.

37. A recent Dutch study reported the fate of POP-BDEs (including BDE-209) in plastic waste streams. In general, POP-BDEs were found in very few single cars, or e-waste. However, BDE-209 was frequently found (92-100%) in the shredded material from e-waste or cars and in recycled plastic pellets (100%) at higher concentrations than other POP-BDEs (IVM, 2013). In Europe, an extended producer responsibility scheme and a scrap vehicle deposit are in place and materials from ELVs are recycled. The overall recycling rate of ELV in the EU reaches 90% (RPA 2014). Sweden reported that

plastic from ELVs usually ends up in the Shredder Light Fraction (SLF), which ismainly incinerated and in some cases landfilled. In Norway, BDE-209 was identified in car upholstery from Asia, in levels of 1.5-2.5% w/w, and the waste components are considered hazardous if they contain more than 0.25% c-decaBDE and incinerated after shredding. Large plastic parts from ELV in Germany are mainly recycled but about 10% are reused. The SLF with high calorific value is incinerated or used for energy recovery, while the low calorific value fraction, which has higher mineral content, can be used for landfill construction or the back-filling of mines (RPA 2014). In the recent Dutch study, BDE-209 was not found in European ELV parts but was detected in 59% of the ELV parts of older US and Asian cars assembled before 2001. Analysed and concentrations ranged from < 2 – 23,000 µg/g (IVM, 2013 and Tables 2and 3, respectively, in UNEP/POPS/POPRC.11/INF/6). Collectively these studies illustrates that sorting out and removing c-decaBDE containing parts prior to destruction and recycling operations would be an important and effective measure to avoid further distribution of c-decaBDE contained in waste. Policies on extended producer responsibility could play a key role in implementing these practices.

38. Destruction of c-decaBDE containing waste in accordance with Article 6.1 d(ii) and 6.2 of the Convention would contribute to the elimination of emissions and exposure from waste. Different techniques for handling POPs-containing waste in an environmentally sound manner are available (Basel Convention 2015a, b, Stockholm Convention 2012a). Controlled incineration, where the FR decomposes in the incineration process, is one way to dispose of waste containing c-decaBDE (ECHA 2014). Incineration at high temperatures is generally considered the effective manner to destroy POPs like c-decaBDE/PBDEs or products containing these chemicals, such as in hazardous waste incinerators and by cement kiln co-incineration (Basel Convention 2015a). Experimental evidence shows that under some conditions, including in state-of-the art municipal solid waste incineration facilities, incineration of POPs waste may lead to formation of polybrominated dibenzo-dioxins (PBDD), polybrominated dibenzofurans (PBDF), brominated-chlorinated diben/o-p-dioxins (PXDD) and dibenzofurans(PXDF)(NCM,2005;ECA, 2011;Stockholm Convention, 2012a;Weber and Kuch, 2003). These incineration products formed from waste containing c-decaBDE may be destroyed at the very high continuous operating temperatures with their emissions to the environment controlled to some extent via the flue gas treatment systems, though contaminated fly ash will also be formed which require disposal in a hazardous waste landfill. The incineration efficiency and the operating conditions of the flue gas treatment systems are of great importance to the resulting emissions of dioxins (NCM,2005;5EBFRIP, 2005).Many countries and regions globally have the capacity to incinerate POPs, such as in hazardous waste incinerators or by co-processing in cement kilns. However, a general overview of the global capacity or the capacity for incineration in specific regions is not available.

39. Where neither destruction nor irreversible transformation is the environmentally preferable option, for waste with a POP content above the low POP content, other environmentally sound disposal techniques may be used. Specially engineered landfills may be one option, however, the long-term fate of c-decaBDE in landfills is not well understood and landfills are believed to be the most prominent c-decaBDE emission source from waste (ECHA, 2014a). Monitoring of landfill leachates has shown the presence of BDE-209 (SFT, 2009; Chen et al., 2013) and BDE-209 was also found to be the dominant PBDE congener in landfill sediments (SFT, 2009). However, currently in many countries landfilling is the most common way of waste disposal, leading to c-decaBDE containing waste accumulating in the landfills (U.S. EPA, 2007). Waste containing c-decaBDE above the low POP content level can be landfilled only in specially engineered landfills, designed to prevent leaching and spreading of hazardous chemicals, as described by the Basel Convention guidance (Basel Convention, 1995, 2015a,b;Stockholm Convention, 2012a). Waste containing c-decaBDE below the low POP content level shall be disposed of in an environmentally sound manner in accordance with pertinent national legislation and international rules, standards and guidelines.

40. An additional concern is sludge (biosolids) from wastewater treatment. This sludge may be used as a fertilizer on agricultural soil and has been found to contain BDE-209 in many instances (de Wit et al.,2005; NEA 2012; NERI, 2003; Ricklund et al., 2008a,b; Earnshaw et al., 2013).In many countries sludge from wastewater treatment plants is incinerated or disposed of in landfill due to high-levels of environmental pollutants.

41. The prevention and minimization of POP wastes are the first and most important steps in the overall environmentally sound management of such wastes. The Stockholm Convention BAT/BEP Guidelines underlines the importance of source reduction including minimization of quantity of wastes and reduction of toxicity and other hazard characteristics (Stockholm Convention, 2012a). In its Article 4, paragraph 2, the Basel Convention calls on Parties to "ensure that the generation of hazardous wastes and other wastes is reduced to a minimum". Waste prevention should be the

preferred option in any waste management policy. According to the framework for the environmentally sound management of hazardous wastes and other waste, the need to manage wastes and/or the risks and costs associated with doing so are reduced by not generating wastes and ensuring that generated wastes are less hazardous (UNEP, 2013a).

42. Another option of waste management is energy recovery. Plastic containing FR can be destroyed in incinerators for energy recovery. Incineration with energy recovery is a process whereby the energy generated during the combustion of plastic waste is recovered and used to produce heat and/or electricity for domestic or industrial use. In the EU, it has been reported that some of the shredded plastic waste fractions from ELV are incinerated for energy recovery (IVM, 2013; RPA, 2014). In Germany in 2010, 40% of the shredded fraction from ELV was incinerated for energy recoverywhile large plastic parts from ELV were mainly recycled and 10% were reused (RPA, 2014).

43. Prohibiting recycling of materials containing c-decaBDE would contribute to the elimination of risks associated with the recycling process and continuing exposure through products and wastes. Waste management measures in line with Article 6 (d) of the Convention to reduce or eliminate releases from stockpiles and waste, including products and articles upon becoming wastes, containing c-decaBDE above the low POP content will be required to reduce emissions of c-decaBDE. POPRC recommendations on elimination of PBDEs from the waste stream note that the objective is to eliminate PBDEsfrom the recycling streams as swiftly as possible. Failure to do so will inevitably result in wider human and environmental contamination and the dispersal of PBDEs into matrices from which recovery is not technically or economically feasible and may result in loss of long-term credibility of recycling (Decision POPRC-6/2).

44. Although materials containing c-decaBDE can be recycled several times with only a small loss of the c-decaBDE content (Hamm et al., 2001; as cited in Earnshaw et al., 2013) this practice will continue to spread c-decaBDE to the environment as well as human exposure. For every year with continuing recycling the number of c-decaBDE containing articles in circulation will increase. The fraction of the recycled plastics used to produce new articles is unknown (ECHA 2014a). However, the more recycled products with low concentrations of BDE-209 there are on the market, the more difficult it will be to identify waste containing c-decaBDE. As a part of the mixed plastic waste to be recycled, plastic containing c-decaBDE will likely spread into new products that will be difficult to track. BDE-209 has been found in products made from recycled plastics, including food contact articles (FCA) (Samsonek and Puype 2013; Puype et al., 2015). In a recent study, BDE-209 was found in FCA such as thermo-cup lids and an egg cutter made from recycled e-waste (Puype et al., 2015). These studies evidently show that products made from recycled material containing c-decaBDE re-enters the market and that some of these, such as toys and FCA, are products that are used in a way that has the potential to pose a threat to human health.

45. Furthermore, some c-decaBDE containing waste ends up in countries that do not have the infrastructure or the technology to dispose waste in an environmental sound manner. Developing countries face economic challenges and lack the infrastructure for sound hazardous waste management, and have particular challenges in this regard (ILO 2012).As environmentally responsible waste management options are highly technological and require high financial investment, there is currently a high level of transboundary, often illegal, movement of e-waste into developing countries for cheaper recycling (SAICM/ICCM.2/INF36).Available estimates of transboundary exports of e-waste are highly variable (reviewed by Breivik et al., 2014). A report published in 2002 by the Basel Action Network, claimed that 50 to 80% of the e-waste collected for recycling in the western USA is exported to Asia, of which 90% is destined for China.Furthermore, it was reported that of the amount of e-waste collected in developed countries and sent for recycling, 80 per cent ends up being shipped (often illegally) to developing countries to be recycled by hundreds of thousands of informal workers (ILO, 2012). Unregulated recycling processes may pose a risk to workers and the public through exposure to toxic chemicals (U.S. EPA, 2014a; Bi et al.,2007; Qu et al.,2007; Tue et al., 2010; Tsydenova and Bengtsson 2011). For example, EEE containing c-decaBDE and other toxic substances are often recycled under conditions which results in a relatively high release of BDE-209 to the environment and contamination of the sites (Zhang et al., 2014), children (Xu et al., 2014) and exposure of workers (Tue et al., 2010). As described above, developing countries lack infrastructure for sound hazardous waste management and waste management is typically dealt with in the informal sector using rudimentary techniques,where open burning and dumpsites are common destinations for c-decaBDE-containing articles and electronic wastes (Li et al., 2013; Gao et al., 2011; ILO, 2012).

46. In the past years, the infrastructure for collecting and recycling electronics has grown considerably, mostly in Europe and parts of Asia, using automated technologies for harvesting metals and plastics from electronics. Between 25% and 30% of the e-waste generated each year is composed of plastic and less than 10% of this plastic is currently recycled. Based on a Dutch mass flow analysis,

22% of the POP-BDE in e-waste is expected to end up in recycled plastics. The same study shows that in the automotive sector, 14% of the POP-BDE is expected to end up in plastics recycling, while an additional 19% is expected to end up in second-hand parts (reuse) (IVM 2013). Furthermore, BDE-209 was detected in 100% of the isolation material and carpet padding tested and in 25 % of the plastic toys; both of these products were made from recycled plastics (IVM 2013). In the U.S. approximately 15-20% of post-use EEE was recycled and between 80 – 85% was disposed of in landfills or incinerated (U.S. EPA, 2007). The situation regarding the management of textile waste in both Europe and other regions is uncertain. The European Chemicals Agency (ECHA) however stipulates that c-decaBDE containing textiles are currently not recycled in the EU (ECHA, 2014a). Based on these findings a restriction on recycling will likely have limited economic implications for the recycling industry.

47. PBDE commercial mixtures penta- and octa are listed in Annex A of the Convention with specific exemptions for recycling. To support Parties in the implementation of strategies to reduce the recycling of materials containing PBDEs, POPRC (Decision POPRC-6/2,UNEP/POPS/POPRC.6/2/Rev.1) outlined a series of recommendations that are relevant to c-decaBDE as well. In summary, POPRC recommended to eliminate PBDEs from the recycling streams as soon as possible. To meet this recommendation articles containing PBDEs should be separated from the waste stream before recycling. Failure to do so will inevitably result in wider human and environmental contamination and the dispersal of PBDEs into matrices from which recovery is not technically or economically feasible. Furthermore, PBDEs should not be diluted since this would not reduce the overall quantity in the environment.

48. In order to sort out c-decaBDE containing wastes for environmentally sound management and to avoid and/or minimize recycling of articles that contain c-decaBDE, effective screening and separation techniques for material containing FR are necessary. When screening and separation techniques are not readily available and concentrations are assumed to be above the low POP level, recycling should be avoided. Furthermore, waste containing c-decaBDE should not be exported to developing countries since there is generally limited capacity or technology to treat the waste in an environmentally sound manner and protection of workers is limited or lacking.

49. Production and down-stream industrial use of c-decaBDE also contributes to the c-decaBDE emissions (UNEP/POPS/POPRC.10/10/Add.2), although emissions in these stages of the life-cycle are generally assumed to be small, the environmental impact of industrial production and use can be high and likely depend on the technology used as well as management practices. The absence of decreasing trends in the environment following voluntary measures by the industry to reduce emissions during production and industrial use (ECHA, 2014a) suggests that implementation of BAT/BEP is not sufficient, and that a ban on production is necessary to fully eliminate c-decaBDE releases in these phases of its life-cycle as well as from articles in use.

50. A ban on the production and use of the BDE-209-component of c-decaBDE, together with waste management measures to reduce or eliminate releases from stockpiles and waste, including products and articles upon becoming wastes, would be an efficient way to eliminate all emissions of BDE-209 and can also considered as the most appropriate option for the phase-out of BDE-209 under the Stockholm Convention.

51. The alternative option would be to list the BDE-209-component of c-decaBDE in Annex A, B and/ or C with exemptions and/or acceptable uses. However, according to the Annex F information submitted by Parties, technically feasible alternatives appear to be available for all applications. However, at a later stage some industry Observers have raised a concern regarding service and replacement of parts in articles already in use and identified a possible need for exemptions in the transportation sector. There may also be need for an exemption for new use in this sector that can be restricted and limited to specific uses, since the aviation and vehicle industry are in the process of phasing out c-decaBDE, and some materials and components could still contain c-decaBDE. In addition, a small number of Parties have suggested the possibility of a need for a recycling exemption.

2.3 Information on alternatives (products and processes) where relevant

52. The U.S. EPA and ECHA recently published comprehensive assessments of chemical alternatives to c-decaBDE (U.S. EPA, 2014a; ECHA, 2014a). The U.S. EPA assessment provides detailed human health and ecological hazard information for 29 substances and mixtures that have been identified as potentially alternatives to c-decaBDE in a variety of applications (see Table 4, UNEP/POPS/POPRC.11/INF/6).The report published by ECHA identified 13 chemicals for further assessment and evaluation as alternatives to c-decaBDE(ECHA, 2014a; see Table 5, UNEP/POPS/POPRC.11/INF/6). Other assessments of alternatives to c-decaBDE have also been conducted in the past (LSCP, 2005; Illinois, 2006;CPA 2007;DME, 2007;ECB, 2007; Washington,

2008; Maine, 2010; ENFIRO, 2013).The research project, ENFIRO,assessed substitution options for selected BFRs by comparing information on hazard and by testing fire-and application performance for different uses.

53. To date, most assessments of alternatives to c-decaBDE/BDE-209 have focused on the replacement of c-decaBDE with alternative chemicals (i.e. a chemical that have flame retardant properties that can be substituted directly for c-decaBDE in articles). However, alternative techniques to improve fire safety also exist and are also described in some of the assessments (ECHA, 2014a; U.S. EPA, 2014a).

54. An overview over the available c-decaBDE alternatives is provided in Sections 2.3.2-2.3.5 below and UNEP/POPS/POPRC.11/INF/6.

55. Presented below (Table 3) are the categories of materials and sectors/products in which c-decaBDE has been or is currently used globally(see also further info in Tables 1, 6, 7 in UNEP/POPS/POPRC.11/INF/6)

Table 3. Summary of polymers where c-decaBDE is used as a FR and their end-use application by category

Polymer Group	End-Use Applications								
	Electronics	Wire and Cable	Public Buildings	Construction Materials	Automotive	Aviation	Storage and Distribution Products	Textiles	Waterborne emulsions & coatings
Polyolefins[1] (PE, PP, EVA)	X	X	X	X	X	X	X	X	X
Styrenics[2] (PS, HIPS, ABS)	X		X	X	X	X	X		
Engineering Thermoplastics[3] (Polyesters (PET, PBT), PA, PC, PC-ABS, PEE-HIPS)	X	X	X	X	X	X		X	X
Thermosets[4] (UPE, epoxies, melamine-based resins)	X		X	X	X	X	X	X	X
Elastomers[5] (EPDM rubber, thermoplastic PUR, EVA)	X	X	X	X	X	X	X	X	X
Waterborne emulsions and coatings[6]	X	X	X	X	X			X	X

Source: U.S. EPA, 2014a (Table 2.3.1)

[1]Polyolefins: polyethylene (PE), polypropylene (PP), ethylene vinyl acetate (EVA).
[2]Styrenics: polystyrene (PS), high-impact polystyrene (HIPS), acrylonitrile butadiene styrene (ABS).
[3]Engineering Thermoplastics: polyesters (polybutylene terepthalate (PBT), polyethylene terephthalate (PET)),polyamides (PA, nylons), polycarbonate (PC) and PC-ABS, polyphenylene ether- high-impact polystyrene (PE-HD), PE ether HIPS.
[4]Thermoset plastics: unsaturated polyesters (UPE), epoxies, melamine-based resins.
[5]Elastomers: ethylene propylene diene monomer rubber (EPDM rubber), thermoplastic polyurethanes (thermoplastic PUR), EVA.
[6]Waterborne emulsions and coatings: acrylic-, polyvinyl chloride (PVC)-, ethylene vinyl chloride- and urethane-emulsion.

2.3.1 Alternative substances

56. Different considerations are relevant when selecting a replacement for c-decaBDE. The Stockholm Convention Article 3 paragraph 3 requires Parties that have regulatory and assessment schemes for new chemicals to take measures to regulate with the aim of preventing the production and use of new chemicals that exhibit the characteristics of POPs. In addition, in accordance with Article 3 paragraph 4, Parties should take the POPs criteria in Annex D into account when conducting assessments of chemicals currently in use. According to the POPRC guidance on alternatives and substitutes, alternatives should moreover be available, accessible, efficient and technically feasible (UNEP/POPS/POPRC.5/10/Add.1). In addition, a replacement substance should ideally not substantially increase costs -neither costs of manufacturing or costs incurred as a result of harm to the environment and human health. For the downstream user, manufacturing costs may however not necessarily be the most critical point when substituting one chemical for another. For example, for engineering polymers, which are materials with exceptional mechanical properties, overall function is considered more important than price (Keml, 2005). Furthermore, in applications where chemical substitutes are being considered, an evaluation should first be conducted to address whether flame

retardancy is needed and if so how appropriate fire safety can be achieved without adverse environmental and human health consequences (ECHA 2014a). For example, and as discussed in chapter 2.3.5 below, in EEE, removing sources of ignition or reducing operative voltage requirements can eliminate the need for FRs (LCSP, 2005).

57. According to ECHA (2014a), the industry's choice of a new substitute chemical "will depend on when a possible further regulatory action is envisaged and the ease with which the alternative can be used to substitute c-decaBDE". In other words downstream users are assumed to be less likely to choose an alternative substance subject to current-or future regulatory risk management. They are also assumed to select a so called drop-in alternative i.e. an alternative substance with similar technical properties to the chemical already in use that can be phased in to the manufacturing process with minimal efforts. Nonetheless, substitution to an alternative chemical may necessitate additional changes in product formulation or movement to different classes of polymers, and product manufacturers transitioning to new FRs may have to test a number of chemicals or chemical combinations to determine if they meet performance requirements in final products (U.S. EPA, 2014a).

58. The hazard profiles generated by the U.S. EPA (U.S. EPA, 2014a; Table 4, UNEP/POPS/POPRC.11/INF/6) show that "some of the chemical alternatives have similar hazard profiles to c-decaBDE; other alternatives have trade-offs in hazard endpoints; some alternatives have preferable profiles compared to c-decaBDE. FRs with similar profiles are persistent, potentially bioaccumulative, and tend to have hazards for carcinogenicity, developmental neurotoxicity and repeated dose toxicity. Other alternatives are associated with the concern for hazard based on different endpoints, for example aquatic toxicity, and present hazard trade-offs when compared to c-decaBDE. The large polymers are anticipated to be safer because their large size limits bioavailability. Unfortunately, their long-term fate in the environment is unknown and halogenated polymers may generate halogenated dioxins and furans during combustion. Combustion by-products are not assessed in the report" (U.S. EPA, 2014a). Similar conclusions may be drawn based on the information on hazard and risk given in ECHA (2014a).

59. Among the different categories of chemical alternatives, BFRs would appear to be able to act as drop in replacements for a wide range of the known c-decaBDE applications (ECHA 2014a; U.S. EPA, 2014a).In addition, viable non-halogenated FR/polymer combinations have been identified as alternatives for most c-decaBDE uses. Some of the non-halogenated FR/polymer combinations may also have better performance than c-decaBDE/polymer (ENFIRO, 2013; see Table 8, UNEP/POPS/POPRC.11/INF/6).

60. From an industrial point of view i.e. a technical and economic perspective focused on manufacturing costs, decabromodiphenyl ethane (DBDPE) is identified as the most feasible replacement substance for c-decaBDE (ECHA 2014a).According to Environment Canada, DBDPE is a cost-effective replacement for c-decaBDE applications relevant to Canadian manufacturers, and a switch from c-decaBDE to DBDPE is said to be "likely ongoing" in USA and Canada (ECHA 2014a).DBDPE is also identified as the most likely substitute to c-decaBDE in the EU (ECHA, 2014a). However, U.S. EPA has identified DBDPE as "high hazard for developmental toxicity", "a high hazard for bioaccumulation", and a "very high hazard for persistence based" on empirical data (US EPA, 2014a). In addition, DBDPE is undergoing substance evaluation in the EU due to its potential PBT/vPvB characteristics (ECHA 2014b, UK EA 2007).Other substances may also act as technically feasible reasonably priced alternatives for specific uses of c-decaBDE. Ethylene bis (tetrabromphthalamide) (EBTBP) is identified as another bromine-containing FR that can replace c-decaBDE in many of its applications (ECHA, 2014a). However, according to ECHA (2014a) which have compared the market price of c-decaBDE to that of its alternatives, information from the supply website Alibaba.com suggests that EBTBP is more expensive than both c-decaBDE and DBDPE. EBTBP may therefore be a less attractive alternative than DBDPE from a cost of manufacturing perspective.

61. While alternative substances for replacing c-decaBDE in plastics, textiles and other uses are further discussed in sections 2.3.2- 2.3.4 below detailed information on the environmental- and health hazards of the c-decaBDE alternatives identified by the U.S. EPA (2014) is provided in Table 4,UNEP/POPS/POPRC.11/INF/6. Similarly, a detailed overview of the 13 alternative substances identified in the EU restriction proposal, their applicability for different uses, price, loading, environmental and health properties and economic feasibility is given in Table 5, UNEP/POPS/POPRC.11/INF/6 (for further details see also ECHA, 2014a).The viable non-halogenated FR/polymer combinations identified in the ENFIRO project are presented in Table 8, UNEP/POPS/POPRC.11/INF/6, while other alternatives identified in the Annex F process are presented in Table 9, UNEP/POPS/POPRC.11/INF/6.

2.3.2 Plastics

62. The plastics industry is by far the major user of FR and the largest quantities of FR are supplied to raw-material manufacturers (Kemi, 2005). The amount of c-decaBDE used in plastics and textiles globally varies but up to 90% of c-decaBDE ends up in plastic and electronics while the remaining ends up in coated textiles, upholstered furniture and mattresses (ECHA, 2014a; US EPA, 2014a). Like any other additives, a FR is selected by the manufacturer for its inherent properties and compatibility with the polymer and to fulfil the specifications of the final product established by industrial customers (e.g. a car or furniture manufacturer).

63. For c-decaBDE in plastics the largest down-stream uses are in EEE applications and include casings for EEE, wire and cable, and small electrical components (U.S. EPA, 2014a; see Table 1, UNEP/POPS/POPRC.11/INF/6). In the U.S., the main reported use was in the front and back panels of televisions made of high impact polystyrene (HIPS) (Levchick, 2010), but c-decaBDE was also used in electronic connectors made from glass-filled PBT or nylons. Other identified uses of c-decaBDE flame-retarded plastics are in buildings, construction materials, in storage and distribution products such as plastic pallets, in the transportation sector (cars, airplanes, trains and ships). Because of the restrictions on the use of c-decaBDE in EEE in important markets like Europe and China, many large electrical- and electronic companies have transitioned away from using c-decaBDE (Kemi, 2005; U.S. EPA, 2014a). End-applications where c-decaBDE has been phased-out include front and back panels of televisions made of HIPS, electronic connectors made from glassed-filled polybutylene terephthalate (PBT) or nylons (Levchik, 2010 in U.S. EPA, 2014a). A ban on EE medical equipment entered into force in the EU on 22 July 2014. However, c-decaBDE flame retarded plastics are still used globally in a variety of EEE including household appliances and tools such as vacuum cleaners (in both the casings and internal components), and washing machines. In these appliances, the housings are typically made from polypropylene (PP), HIPS or ABS (U.S. EPA 2014a; Levchick, 2010). Another use that is still ongoing globally is in small electrical parts, such as light sockets or decorative lights and wires and cables which are usually made from high density polyethylene (PE), PP or polyphenylene (PPE) (U.S. EPA, 2014a; Levchick, 2010). Globally c-decaBDE is also still used in the plastics PBT and polyamides (PA), which are found in electrical, automotive, and plumbing parts such as housings, switches and other smaller internal parts of larger electrical equipment (Weil and Levchik 2009). For most plastic polymer applications where c-decaBDE is commonly used other FRs are available and already applied (Kemi 2005).

64. The aviation industry still uses c-decaBDE in electrical wiring and cables, interior components, and EEE in older airplanes and spacecraft's. In the transport sector, c-decaBDE continues to be used in plastics for EEE, reinforced plastics, under hood and in inner parts as well as in the interiors of cars. It is also used in other means of transportation (U.S. EPA, 2014a; see Table 1, UNEP/POPS/POPRC.11/INF/6). Most of the flame retarded plastics used in vehicles are found in the engine compartment (often polyamides). In addition, the firewall between the engine and the cabin is an important flame retarded part. However, it should be noted that in Europe fire-safety requirements for vehicles are not very strict and most of the automotive plastics are therefore not flame retarded (IVM, 2013). Whether this is the case also in other global regions is unknown.

65. C-decaBDE is reportedly still used in toys in China (Annex F China; Chen et al. 2009), and in the synthetic rubber industry as a FR in conveyor belts for use in mines, including underground coal mines, and in the manufacture of ventilation bands used as seals around air ducts in mine ventilation systems (Annex F Australia). Until recently, c-decaBDE was also used in plastic shipping pallets in the U.S. (U.S. EPA, 2014a), but the company producing these pallets is no longer in business (U.S. EPA, personal communication) and three U.S. states (Maine, Oregon and Vermont) have prohibited the manufacture, sale and distribution of shipping pallets containing c-decaBDE (Maine, 2008; Oregon, 2011; Vermont, 2013).

66. For plastics in EEE, substitution strategies range from exchange of the resin system and FR, to complete redesigns of the product itself. Alternative techniques such as redesign are further described in section 2.3.3 below. According to the EU restriction proposal, which assessed different alternatives to c-decaBDE, eight possible alternative chemicals appear to be possible substitutes for c-decaBDE in plastic polymers (ECHA, 2014a):

(a) Decabromodiphenyl ethane (DBDPE);

(b) Bisphenol A bis(diphenyl phosphate) (BDP/BAPP);

(c) Resorcinol bis(diphenylphosphate) (RDP);

(d) Ethylene bis(tetrabromophthalimide) (EBTBP);

(e) Magnesium hydroxide (MDH);

(f) Triphenyl phosphate (TPP);

(g) Aluminium trihydroxide (ATH);

(h) Red phosphorous.

67. In addition, the Paxymer® FR system is reported as an alternative to c-decaBDE in polyolefin plastics (Annex F Paxymer AB). Paxymer® is a POPs-free product (UNEP-POPS-COP.5-INF-34). According to information from the manufacturer Paxymer AB, Paxymer® is not persistent, bioaccumulative and toxic (PBT) or carcinogenic, mutagenic and toxic to reproduction (CMR), and is not an endocrine disruptor (EDC).However, it should be noted that the information provided by the manufacturer about the chemical identity and the environmental- and health properties of this system has not been verified by independent sources. Moreover, ICL-Industrial Products (ICL-IP) report the availability of a polymeric brominated epoxy FR additive (F-2100) suitable for use in polybutylene terephthalate (PBT) and polycarbonate (PC)/acrylonitrile butadiene styrene (ABS) alloys, including construction applications (Annex F ICL-IP). An overview of plastic polymers containing c-decaBDE and the alternative FRs for these uses, including down-stream applications, is provided in Tables 5-9, UNEP/POPS/POPRC.11/INF/6. As indicated previously the most likely is reported to be DBDPE (ECHA, 2014a; U.S. EPA, 2014a; Environment Canada, 2014).

68. Detailed information on uses/applications, loading, costs and hazard for the identified alternatives to c-decaBDE in plastics, is reported in Tables5and 9, UNEP/POPS/POPRC.11/INF/6. Typically c-decaBDE is used in plastics/polymers at loadings of 10-15% by weight, though in some cases loadings as high as 20% have been reported (ECHA, 2012c). According to the manufacturer, Paxymer ® has excellent, proven performance in PP and PE with addition levels ranging from 2-32% depending on the downstream application and use. Reported loadings and cost for other alternatives used in plastics range from 1-60% and 1-12 €/kg respectively (see Tables 5and 9, UNEP/POPS/POPRC.11/INF/6).

69. In certain uses, plastics have to fulfil fire safety regulatory requirements as mandatory specifications. Compliance with the fire requirements for plastics is controlled with well-defined flammability tests such as the International Electrotechnical Commission (IEC), or in the regulations and approval procedures of the Underwriters' Laboratories Inc. (UL), the latter mainly operating on the US market (KemI, 2005). However, although these fire regulations are mandatory for the market, there are no fire regulations that require the use of certain FRs in order to comply with these standards or regulations. Hence, it is up to the manufacturers to decide which technique to use. The ideal chemical FR for plastics should be compatible (i.e. not alter the mechanical properties of the plastic), not change the colour of the plastic, have good light stability, and be resistant towards ageing and hydrolysis. Further, an ideal chemical FR should match and begin its thermal behaviour before the thermal decomposition of the plastics, not cause corrosion, not have harmful physiological effects, and not emit or at least emit low levels of toxic gases. It should ideally also be as cheap as possible. However, as indicated earlier, function is generally more important than price for engineering polymers and price is not necessary the most important factor when selecting an alternative (KemI, 2005). As indicated above fire safety requirements for vehicles in Europe are not very stringent. Most European car manufacturers nonetheless follow the safety standard of the European New Car Assessment Program, Euro NCAP, which is stricter than the standard required by law (IVM, 2013, see alsowww.euroncap.com/home.aspx).

70. In summary, efficient and technically feasible alternatives to the use of c-decaBDE as a FR in plastics (and synthetic rubber) are available and accessible on the market (ECHA, 2014a). DBDPE may be the most likely chemical substitute for c-decaBDE in most plastics, but other of the above mentioned alternatives or non-chemical techniques may offer a more sustainable long-term alternative to c-decaBDE than DBDPE.

2.3.3 Textiles

71. C-decaBDE has traditionally been applied to textiles as a back-coating in combination with antimony oxide (ATO) as a synergists (LCSP, 2005). Halogen-ATO can only be applied topically in a resin binder. C-decaBDE is first mixed with ATO to form an aqueous dispersion, which is then mixed with a polymer emulsion containing e.g. natural or synthetic rubber, EVA, styrene-butadiene copolymer or PVC (ECHA, 2012c). The c-decaBDE/ATO FR mix can account for 18 to 27% of the total weight of the product (Washington, 2006) Lighter fabrics usually require higher FR loadings than heavier fabrics. Fire resistant back-coatings are effective on a wide range of fabrics, including polyamide/nylon, polypropylene, acrylics, and blends such as nylon–polyester.

72. In the U.S. c-decaBDE is used in textile applications for transportation (public transit buses, trains, aviation and ships), in draperies for use in public occupational spaces, in furniture of high-risk occupational areas such as nursing homes, hospitals, prison and hotels, and in military for tarps, tents and protective clothing, but are not used in consumer clothing (LCSP 2005;BSEF 2007 as cited in U.S. EPA,2014a). However, in several U.S. states the use of c-decaBDE in residential upholstery and mattresses is no longer allowed (LCSP, 2015). In the EU, c-decaBDE is also used in domestic draperies and furniture (in foams, fillings and back-coatings, predominantly in countries with certain fire safety standards such as the UK (ECHA, 2014a).In Japan,vehicle seats accounts for 60% of the c-decaBDE use while an additional 15 % is reportedly used for other textile applications(Sakai et al., 2006).According to U.S. "furniture industry sources" in 99% of cases, chemical FRs will not be needed to meet pending national standards for residential upholstery (Illinois, 2007; Maine, 2007a). The same may be true in Europe. When testing 320 combinations of 20 cover fabrics and 18 fillings of upholstered furniture for the EU market, 38% of the combinations without FRs passed both match and cigarette test, and in the group that passed only cigarette test the FR-free combination accounted for 62% (CBUF as cited in Guillaume et al., 2008).

73. The lack of labelling, and information on FR use in consumer products make it difficult to assess human exposure sources. Various eco- or green-labelling certifications may indicate that the product is FR-free. However, FRs are still widely used in furniture. For example, in a study analysing 102 polyurethane foam samples from residential couches purchased in U.S from 1985 to 2010, FRs were detected in 85% of the samples. For sofas purchased after the global ban on pentaBDE in 2005, tris (1,3-dichloroisopropyl) phosphate (TDCPP) was detected in 52%, and components associated with the Firemaster550 mixture were detected in 18% of the samples. In addition, a mixture of non-halogenated organophosphate FRs were observed in 13% of the samples (Stapleton et al., 2012). The textile covering the foam, which is where c-decaBDE could be expected was not analysed in this study.

74. Substitution of c-decaBDE in textiles is not straight forward due to the complexity of the end-products and the wide array of possible substitution approaches. These approaches include substitute FRs, alternative fibres, inherently fire resistant fibres, barrier layers, and nonwovens. However, a number of affordable options are available to replace c-decaBDE uses in furniture, mattresses, draperies and other textile applications. Substitution options for textiles range from brominated additive FRs such as DBDPE, to alternative techniques and inherent flame-resistant materials, which are described in Section 2.3.3 of the present document.

75. Based on its technical compatibility with existing processes and its price compared to c-decaBDE several European industry stakeholders have confirmed that DBDPE would be the preferred alternative to c-decaBDE in textiles (ECHA, 2014a; RPA, 2014; Klif, 2008). However, a focus on "drop-in" solutions may limit the innovative thinking that is needed to find effective and environmentally sound solutions (LCSP, 2009).

76. Some c-decaBDE substitutes exist for synthetics, but their water solubility results in limited durability as they "wash out" during laundering. Natural fibres are easier to chemically flame retard than synthetics, and there are several chemical non-halogen c-decaBDE substitutes available for natural cellulose fibres such as cotton, wool, rayon (viscose, modal and lyocell), and linen. They include:

(a) Ammonium polyphosphates;

(b) Dimethylphosphono (N-methylol) propionamide;

(c) Phosphonic acids such as (3-{[hydroxymethyl]amino}-3-oxopropyl)-dimethyl ester;

(d) Tetrakis (hydroxymethyl) phosphonium urea ammonium salt.

77. Co-polymerization refers to inclusion of an additive in the fibre melt spinning process which makes the FR a physically part of the fibre matrix. The most common FR for polyester is polyethylene terephthalate with built-in phosphorus on the polyester backbone. This modified polyester is used in the majority of textile applications, is wash resistant, and is thought to be a good substitute for the c-decaBDE/antimony flame retardant. Polyester accounts for 30% of the world fibre production (see Figure 1, UNEP/POPS/POPRC.11/INF/6). Applications include clothing and draperies. Draperies that employ inherently flame resistant polyester can be laundered in water since the phosphate FRs are part of the polymer backbone and are not water soluble (LCSP, 2005).

78. Both ECHA (2014a) and U.S. EPA (2014a) have considered risk-hazard information on the identified alternatives. While there is no single replacement for c-decaBDE for textiles applications (Table 11 and 12, UNEP/POPS/POPRC.11/INF/6), the multitude of options on the market make it

clear that viable approaches exist (LCSP, 2005). The identification of several halogenated and non-halogenated FRs in a study of chemicals commonly used in textile strengthen this (Kemi, 2014, see Table 13, UNEP/POPS/POPRC.11/INF/6). The following seven substances were identified as the most likely chemical alternatives to the use of c-decaBDE in textiles (ECHA, 2014a):

(a) Aluminum trihydroxide (ATH);

(b) Magnesium hydroxide (MDH);

(c) Tris(1,3-dichloro-2-propyl) phosphate (TDCPP);

(d) Ethylene bis(tetrabromophthalimide) (EBTBP);

(e) 2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide;

(f) Tetrabromobisphenol A bis (2,3-dibromopropyl ether) (TBBPA) (only in polymer applications);

(g) Red phosphorous;

(h) Decabromodiphenyl ethane (DBDPE).

2.3.4 Other uses

79. In addition to the use in textiles and plastics c-decaBDE is used in sealants, adhesives, architectural foam, and coatings as well as in some applications in buildings and construction. C-decaBDE is used in wall and roof panels, which are typically made from unsaturated polyester (UPE) glass composites; floor tiles; and commercial grade carpeting. C-decaBDE is also used in e.g. in insulation materials, foamed polyolefins, and in roofing materials such as membranes and films for use under roofs to protect building areas (Table 1, UNEP/POPS/POPRC.11/INF/6). C-decaBDE can also be found in ducting elements such as the duct covering or insulation. The EU restriction proposal for c-decaBDE identified the following six chemicals as alternative substances for these applications:

(a) Magnesium hydroxide (MDH);

(b) Aluminum trihydroxide (ATH);

(c) Ethylene bis(tetrabromophtalimide) (EBTBP);

(d) Substituted amine phosphate mixture (P/N intumescent systems);

(e) Red phosphorous

(f) Decabromodiphenyl ethane (DBDPE).

2.3.5 Alternative techniques and inherent flame-resistant materials

80. Alternatives that eliminate the need for chemical FRs through material substitution or design while meeting relevant fire safety standards and performance requirements are preferable, especially when they include chemicals of low toxicity and contain recyclable or compostable materials (New York State, 2013). The assessments of technical and economic feasibility of alternatives to c-decaBDE are primarily focused on alternative chemicals that directly can substitute c-decaBDE in articles (Section 2.3.2 above). However, flame retardancy can be achieved through the use of alternative techniques such as inherent flame-resistant material, use of different technical solutions i.e. barriers or complete redesign of the product.For example, power supplies can be shielded with metal to eliminate FRs or even be removed from the product as has been done with printers and rechargeable phones (LCSP, 2005). Inherent flame-resistant materials can meet fire code standards without special processing or chemical additives. Furthermore, the protection is incorporated into the fibres and is less likely to be worn away or washed out (DuPont, 2010). The mentioned alternative techniques can be used in a multitude of materials and applications, and are used in textiles, electronics, aircraft, and ground transportation vehicles and may be used in place of c-decaBDE in some instances. Examples of different alternative techniques, their attributes, and end-use products relevant to this assessment are given in Tables 14 and 15, UNEP/POPS/POPRC.11/INF/6.

Plastics

81. An alternative to the use of chemical FRs is redesign of the product itself. Redesign has successfully replaced c-decaBDE in several EEE applications. Redesigns of the product such as (i) separating high-voltage components that need greater ignition protection from low-voltage components and (ii) reducing operating voltage requirements and therefore reducing the need for flame-retarded enclosure materials.

82. Another product redesign alternative is to remove the power supply from the product. This is common in many devices including printers and rechargeable phones. These separate power supplies are typically black boxes connected to the power cord but not included in the unit itself. The separate power supply reduces the fire retardancy requirements of the electronic enclosure. To change product designs and their implementation would require a higher level of research and development activities than the substitution of c-decaBDE with an alternative chemical FR but is more sustainable as a long-term alternative.

83. Metal or inherently flame-resistant plastic can be used as alternative materials in certain electronic products. Options that eliminate the need for FRs through material substitution while meeting fire safety standards and performance specifications are considered preferable, particularly when product materials are derived from chemicals of lower toxicity and the products and/or materials are able to be recycled or composted (CPA, 2015).Material substitution that eliminates/reduce the need for chemical FRs has been shown possible by Apple Inc., which phased out BFRs (including c-decaBDE) in many of its computer products such as laptops, computer monitors, central processing units and servers (Apple Inc.). Apple Inc. replaced electronic encasements previously made of polycarbonate with encasements made of aluminium alloy, thereby eliminating the need to use FRs(Apple Inc.).A number of international producers of electronic equipment (Ericsson Network Technologies, Electrolux, IBM, Atlas Copco, Sony Ericsson, and Hewlett Packard) reported that they have phased-out- or never used c-decaBDE in their products (KemI, 2005).

84. Introduction of flame resistant metal barriers that separate or isolate the most flammable parts from the rest of the product and eliminates the need for FRs such as c-decaBDE has also been shown (LCSP, 2005).

85. In the EU assessment (ECHA, 2014a) various alternative techniques that could be used to replace c-decaBDE as a FR in plastics were identified. These include intumescent systems, nanocomposites, expandable graphite, smoke suppressants, polymer blends, use of inherently flame retardant materials and product redesign. These alternatives techniques are described in detail in Table 14 of UNEP/POPS/POPRC.11/INF/6. Another option is layering where an article is produced using layers of highly FR filled polymer and low or non-flame retarded polymer. This apparently gives a similar level of fire performance as would be achieved if the entire polymer had been treated, while helping to retain the mechanical properties of the polymer (ECHA, 2012c).

86. The use of inherently flame retardant materials is an additional alternative technique that can be considered. Halogenated polymers such as PVC have FR properties because they release halogen radicals during combustion. The effect is often enhanced by the addition of synergists such as ATO to halogenated polymer blends. However, like BFRs may PVC form dioxins and acids upon combustion and are therefore not a preferred alternative FR material (Blomqvist et al., 2007a). The following are polymer materials that are inherently flame-retardant and which might be considered as a substitute to c-decaBDE-based polymers like poly(butylene terephthalate) (PBTE) or polyamide/ nylon (PA) (DME, 2006):

(a) Halogen-free polyketone (this is considerably more costly than PBTE and PA);

(b) High performance thermoplastics such as polysulphone, polyaryletherketone (PAEK) or polyethersulphone (PES)

87. For certain uses, inherently flame retardant materials can include re-design solutions using metal enclosures and others. Polymers that char such as polyimides, polyaramides, liquid crystal polyesters, polyphenylene sulphide, polyarylenes and many thermosets also tend to have a greater resistance to fire. Where the base polymer has FR properties, depending on the end use, a sufficient level of fire performance may be achieved without the need for chemical FRs or much lower loadings may be required (ECHA, 2012c).

88. Some examples of new inherently flame retarded materials are mentioned in literature or in commercial websites, and these are often promoted as replacements for c-decaBDE (ECHA, 2012c; Albemarle, 2013; Great Lakes, 2013; PR Newswire, 2010). It may be necessary to change product designs to adopt these alternative materials and their implementation would require higher level of research and development activities than the substitution of c-decaBDE with a FR drop in chemical replacement. However, a safer environmental and public health profile are additional benefits.

Textiles

89. An alternative approach to achieve flame retardancy in furniture is redesign of products to incorporate non-flammable materials or barrier technologies (LCSP, 2005). Product design choices can successfully meet all current and pending fire safety standards. Two approaches are suitable: 1)

use of cover fabrics made from materials that are inherently fire resistant, 2) use of fire-resistant barriers between the cover fabric and the flammable cushioning foam.

90. There is a tremendous variation in the flame resistance of various fibres and fabrics. FR use in textiles can be avoided if the material itself is non-flammable or has low flammability. A number of synthetic fibres are inherently flame resistant, including aramid, viscose, novoloid, polyamides, and melamine. Some of these fibres are starting to be significantly used in furniture upholstery and mattresses. Traditionally, they have been used to meet the strictest standards for applications such as fire fighter turnout gear, clothing for astronauts, and clothing for race car drivers. Inherently flame resistant fibres like polyhaloalkenes contain halogens such as polyvinyl chloride and vinyl bromide, while others are halogen free, including polyaramides and melamine fibres (LCSP, 2005;see Table 10, UNEP/POPS/POPRC.11/INF/6).Other inherently flame-retarded materials include rayon with a phosphorus additive, polyester fibres, and aramids (Weil and Levchik, 2009). Furthermore, some natural materials like leather and wool have inherently fire-resistant properties. Depending on the tightness of the weave, they can meet fire safety requirements without any additional FR treatment. Some natural materials such as wool may therefore be used as barrier materials in furniture (Klif, 2011).

91. Blending natural and synthetic fibres is another approach since the natural fibres are more effectively flame retarded. Fibre blending is a common method of reducing the flammability of flammable fibres. Polyester is usually blended with cotton and this 'poly-cotton'blend, can pass the simple vertical strip flammability test, if it has lower than 50% polyester content. Furthermore, cotton-nylon blends are commonly used to reduce the flammability of cotton (Gnosys et al., 2010) as well as cotton or polyester blended with melamine. Some fabrics for upholstery, mattresses and drapery are made from blends of several inherently fire resistant fibres mixed with fibres of lower flame performance. In some cases, fibres with a better "feel" such as cotton or polyester can be combined with more flame resistant fibres, such as melamine, to form a fabric that performs well in both comfort and fire performance (LCSP, 2005).

92. An important aspect of furniture and mattress fire protection is the use of barriers between the surface fabric and the interior foam core. In mattresses, industry has made a shift and fire resistant barriers are now commonly used (Maine 2007b; IKEA 2014). Fire barriers are made from inherently flame-retarded fibres such as wool, para aramids, melamines, modacrylics, or glass fibre, and do not rely on the use of flame retardant chemicals. Moreover, many of these fibres are made from non-halogen materials. Some barriers can also be made of blends of inexpensive fibres and expensive inherently fire-resistant fibres. These barriers protect the mattress, futon or box spring core material from combustion. They fully encapsulate the interior materials and must be combined with fire-resistant border seams, tape, and threads (LCSP 2005). In addition to the use of fibre blends, many manufacturers use cotton-batting materials treated with boric acid. These cotton materials are the lowest-cost barrier technology and are used to help meet fire safety requirements. However, the use of boric acid is of concern since it is suspected to be a human reproductive toxicant. Animal studies have reported adverse effects on reproduction in rats and mice exposed to dietary boric acid prior to- and during mating (Weir and Fisher 1972; NTP 1990 as stated in New York State Department of Health 2013). Plastic films have also been used as barriers, especially films made of inherently flame-resistant plastics such as neoprene (polychloroprene) (LCSP, 2005).

93. In textiles, like in plastics, fire safety may also be achieved by the use of intumescent systems (Klif,2011; U.S. EPA, 2014a). Intumescence is the formation of a foamed char, which acts as heat insulation. An intumescent system is generally a combination of a source of carbon to build up char, an acid generating compound and a decomposing compound to generate blowing gases to produce foamed char (Weil and Levchik, 2009). This foam attains a thickness of 10 to 100 times that of the originally applied coating and insulates the substrate material through its low thermal conductivity, making intumescent systems efficient at reducing flammability and the exposure of fume gases (Keml, 2006). Several intumescent systems linked to textile applications have been on the market for about 20 years, and have successfully shown their great potential. Intumescent systems include use of expandable graphite impregnated foams, surface treatments and barrier technologies of polymer materials (Klif, 2011). Intumescent systems may not be applicable to the same sets of textiles as BFR-based back-coatings.

2.3.6 Fire-safety standards, requirements and solutions

94. Society needs systems to reduce and prevent fires and protect human lives. Fires cause injury, deaths and destruction of properties worldwide every year. On the other hand, in countries with stringent fire safety regulations the use of some FRs and resulting environmental contamination and human body burden is reportedly higher than in other countries with more flexible regulations for the

fulfilment of the fire requirements (Klif, 2011). This indicates that awareness about these issues is important when seeking to replace hazardous FRs.

95. A study comparing fire statistics from Europe, the USA and New Zealand concluded that smoking and cooking, in combination with the presence of upholstered furniture and textile, are the most common cause and accident pattern in fatal domestic fires (NIFV, 2009). Men, children and elderly are the most frequent victims, and alcohol use is another major aspect of fatal domestic fires. Most fatal fires occur in the living room or bedroom at night during the weekend and involves (upholstered) furniture, textiles, technical appliances or clothing. In Europe, upholstered furniture played an important role in almost 50% of all fatalities in domestic fires, and in USA upholstered furniture first ignited in 18% of home fire deaths (ACFSE, 2001; NFPA, 2013). Polyurethane foam from upholstered furniture is a major contributor to increased toxic smoke (Molyneux et al., 2014; Stec et al., 2011). Statistics from Norway indicate that 23% of all the domestic fires start in the kitchen while 19 and 9 % start in the living room and bedroom, respectively containing upholstered furniture (NFPA, 2014).

96. The fire performance of a material or product is mainly tested for ignitability, ease of extinguishment, rate of flame spread, rate of heat release and smoke formation (Weil and Levchik 2009). The fire requirements of products are often dependent on the intended use (e.g. higher requirements for institutional buildings compared to domestic houses). Typically, fire regulations prescribe the use of verified technical standards developed by standardisation organisations such as ISO, International Electrotechnical Commission (IEC) or European Committee for Standardization (CEN) and safety consulting and certification companies such as the Underwriters' Laboratory INC (UL). However, neither national fire-safety regulations nor technical standards require use of specific FR chemicals to meet fire safety requirements. Furthermore, performance of products in these test standards does not always correlate to performance in a practical fire situation.UK, Ireland and California previously relied on open flame tests for upholstered furniture, which led to a higher use of BFRs and increased body burdens (UNEP/POPS/POPRC.10/10.Add.2, UNEP/POPS/POPRC.10/INF/6). The test guidelines for the UK regulation are now under revision. A possible change from the current "match- and cigarette test" that requires fabric covers to be tested over non-combustion-modified polyurethane foam, to tests that require the actual final composite to be assessed for fire performance (DBIS 2014). DBIS believes this will give a reduction of up to 50% of FR currently used. Californian furniture flammability standards have been changed such that future use of FRs can be excluded (TB117-2013).

97. FRs can temporarily slow the spread of fires and subsequent heat release for a short time but they may also increase the toxicity of emissions. Toxic emissions may be reduced by introducing a barrier material in combination with the FR. Fire toxicity is the largest cause of death and injury in fires but is usually not taken into account by regulators. Several toxic gases are produced during fire, some of which are linked to the presence of BFRs while others are not. Combustion of materials containing halogenated FRs during accidental fires and burning flame-retarded waste can increase the toxicity of fire effluents by increasing the release of CO, acid gases such as hydrogen bromide, and brominated and chlorinated dioxins and furans (Simonson et al., 2000; Blomqvist et al., 2007b, Shaw et al., 2010). Furthermore, studies indicate that BFRs in combination with antimony produce high yields of CO and HCN, two main asphyxiants in fires (Molyneux et al., 2014; Stec et al., 2011). An overall reduction of flame-retarded materials may therefore lead to a smaller risk of health problems for the general public and fire fighters, if fire safety can be achieved by other means. In line with these findings, the overall fire safety benefit of using these substances to fulfil fire safety requirements has been questioned by a group of scientists (Jayakody et al., 2000; DiGangi et al., 2010).

98. In domestic and institutional buildings, fire safety can be strengthened by yearly educational campaigns focusing on safe use of electric components, candles, fireplaces, stoves, and new generation smoke detectors etc. Requirements of easy access to escape routes and fire-fighting equipment such as fire hose, automatic sprinklers, fire extinguishers and fire-blankets are important measures to prevent and reduce loss from fires and to ease the escape from burning buildings. A further safety solution include the "reduced ignition propensity" (RIP) cigarettes which are meant to be self-extinguishing when left unattended. This has apparently reduced cigarette fire fatalities by41% in New York State. This is now mandatory in all the U.S., Canada, Australia and the EU. Child resistant lighters have also been mandatory in EU since 2006 (WHO, 2014). Solutions for electrical products could include a built-in heat sensor that shuts off the object if it becomes too warm. Regular control and changing of electrical wiring system are also fire preventive.

99. During storage e.g. in warehouses, fire safety can be strengthened by management practices. According to Annex F information from IPEN, fire safety when using plastic pallets may be met

without FRs by implementing systems such as pallet storage management practices (e.g. how high the pallets are stacked and how close together stacks of pallets are) and/or by using sprinkler systems.

100. According to information provided by the aviation industry, aerospace products are subject to stringent airworthiness regulations and certification specification which set performance standards, including flammability. These fire resistance- and safety requirements are intended to prevent and/or control fires both in flights, where options for escape are limited and post-crash, where evacuation from fuel-fed fires is the primary concern. These drive the choice of substances to be used. Aircraft parts and components are expected to withstand fire for a specified time depending on the area and application and materials used in interiors must not generate toxic smoke or excessive heat when on fire. For these reasons materials such as FRs is applied in hot and fire sensitive areas (e.g., around engines) (Boeing Company, pers. comm.).

2.4 Summary of information on impacts on society of implementing possible control measures

101. A positive impact on human health and the environment can be expected from a global reduction or elimination ofc-decaBDE.POPRC-10 concluded that BDE-209, the main constituent of c-decaBDE, at present exposure and effect levels are likely to lead to significant adverse human health and environmental effects as a result of its long-range environmental transport such that global action is warranted (UNEP/POPS/POPRC.10/10/Add.2).

2.4.1 Health, including public, environmental and occupational health

102. BDE-209 is widely detected in the global environment and some species have high body burdens, in particular some species of birds, but also otter and fox living in urban and suburban areas (UNEP/POPS/POPRC.10/10/Add.2). Furthermore, in some organisms such as frogs, fish and birds BDE-209 levels are close to or within the range of reported effect concentrations for developmental-, neurotoxic- and endocrine disruptive effects. BDE-209concentrations in Arctic cod, a key species of Arctic ecosystems, were reported to be at a level that can lead to adverse effects, which in turn can have a negative impact on Arctic cod populations and the whole Arctic ecosystem. Adding to this concern is the potential for low-dose and combined effects between BDE-209 and other similarly acting PBDEs as well as the potential for multiple stressor effects (UNEP/POPS/POPRC.10/10/Add.2,UNEP/POPS/POPRC.7/INF/16). A positive impact of imposing control measures is a decrease in emissions, which over time will reduce exposure and bioaccumulation in humans and wildlife. A global ban or restriction of c-decaBDE is therefore a measure that will contribute to protect and preserve Arctic organisms and ecosystems, which are considered to be at particular risk from POPs (AMAP 2009; UNEP/POPS/POPRC.7/INF/16).

103. Within a short time period, the most positive effect of imposing global control measures would possible be on the indoor environment and public health; with c-decaBDE levels in dust being reduced and ultimately eliminated by ending the use in indoor textiles and equipment. Imposing control measures would also ensure that levels in agricultural products like milk/milk products, various meat products and fish decrease over time. In humans, exposure to BDE-209 takes place already in the early phases of human development and continues throughout life. It is found in human blood, plasma, breast milk and it is transferred to the foetus via the placenta during critical stages of development. The main sources for human exposure presently known are dust and contaminated food (UNEP/POPS/POPRC.10/10/Add.2). Due to their hand-to-mouth behaviour, infants and toddlers have higher body burdens of BDE-209 and other PBDEs than adults and have been identified as vulnerable groups that could be at risk, particularly due to the neuroendocrine and neurodevelopmental toxicity observed in animal studies (UNEP/POPS/POPRC.10/10/Add.2). Eliminating or restricting the use of c-decaBDE will therefore be particularly beneficial for the developing child.

104. Eliminating or restricting the use of c-decaBDE will also lead to better protection of worker health, particularly in developing countries where personal protection equipment is limited, and will also reduce human and environmental exposure to toxic degradation products including lower brominated PBDEs, brominated dioxins and furans (PBDD/PBDF), pentabromophenol and hexabromobenzene. Toxic degradation products, including PBDD/Fs may be formed different ways; during thermal processing (extrusion, molding and recycling), plastics production, photolysis, food preparation (cooking of fish) and waste disposal (Vetteret al., 2012;Kajiwara et al., 2008, 2013a,b; Hamm et al., 2001; Ebert and Bahadir 2003; Weber and Kuch 2003; Thoma and Hutzinger 1987; Christiansson et al.,2009;UNEP/POPS/POPRC.6/INF/6).Regarding occupational exposure, elevated BDE-209 levels have been reported in a number of professions (UNEP/POPS/POPRC.10/10/Add.2).Moreover, a study of 12 firefighters in the U.S. showed that they had elevated BDE-209 concentrations in their blood (contributing >50% of total PBDE concentration in serum) as well as elevated amounts of PBDD/Fs (Shaw et al., 2013). The authors of the study "suggested that PBDD/Fs may contribute substantially to dioxin-like toxicity in individual

firefighters", and that occupational exposure to these compounds during firefighting is significant. Thus, the exposure is likely to contribute to adverse health outcomes, an assumption underpinned by data also from other studies were firefighters are known to have elevated rates of cancer including four types that are potentially related to exposure to PCDD/Fssuch as multiple myeloma, non-Hodgkin's lymphoma, prostate, and testicular cancer (Hansen et al., 1990; IARC 2010; Le Masters et al., 2006;Kang et al., 2008). On the other hand studies suggest that when appropriate measures are in place, such as personal protection equipment and a ventilation system, exposure can be significantly reduced. A recent study showed that by applying appropriate risk management measures in a Swedish electronics recycling facility BDE-209 does not pose a risk to worker's health (Rosenberg et al., 2011; Thuresson et al., 2006). However, worker's in developing countries and countries with economies in transition are likely to be more exposed to BDE-209 and other substances than workers in developed countries because risk reduction measures are typically not in place (Tsydenova and Bengtsson, 2011;UNEP/POPS/POPRC.10/10/Add.2;ILO 2012).

105. C-decaBDE levels are generally highest near wastewater discharges and in areas around electronic waste and recycling plants (UNEP/POPS/POPRC.10/10/Add.2). Environmentally sound management of waste is therefore important in order to achieve an adequate level of protection of human health and the environment. This is in particular important in developing countries where waste handling often occurs under primitive conditions without the use of modern industrial processes, and where worker protection is often inadequate. Considering the wide use of c-decaBDE in EEE, and that e-waste is the world's fastest growing waste stream (StEP,2013). EEE and e-waste is of particular concern. Last year nearly 50million tonnes of e-waste were generated worldwide, about 7kg for every person on the planet. Furthermore, millions of tonnes of old electronic goods are exported illegally to developing countries and countries with economies in transition, primarily to South-East Asia, and to an increasing degree West Africa and Eastern Europe. Increasingly, Senegal, Uganda, Morocco, Colombia, Peru, Kenya, South Africa, Cambodia and Iraq are also destinations for e-waste (Ni and Zeng, 2009; Zoeteman et al., 2010; Schluep et al., 2009 in ILO 2012). Treatment in these countries usually occurs in the informal sector, causing significant environmental pollution and health risks for local populations. Women and children constitute a significant proportion of the workforce (ILO 2012). In China, which today receives the highest proportion of all e-waste globally, levels of BDE-209 in soil at e-waste sites and recycling plants are very high (ILO 2012;Wang et al.,2010, 2011a,b, 2014; Gao et al., 2011, Li et al.,2013). In addition to the occupationally exposed dismantlers, people residing near production and recycling facilities also have elevated blood levels of BDE-209 (see UNEP/POPS/POPRC.10/10/Add.2). In Bangladesh and Nicaragua, children living and working at a waste disposal sites have a combination of BDE-209 and other hazardous chemicals in their blood (Linderholm et al., 2011;Athanasiadou et al., 2008).Open burning of e-waste containing PBDEs is moreover estimated to release tons of PBDD/Fs and PCDD/Fs into the environment (Zennegg et al., 2009). Ma et al., (2009) reported that TEQPBDD/F concentrations from an e-waste recycling facility in China exceeded the TEQPCDD/F concentrations in environmental samples. Moreover, c-decaBDE-containing plastic e-waste also find their way to food contact articles made from recycled plastics where it contributes to human exposure and risk (Samsonek and Puype 2013; Puype et al., 2015). Although recycling of materials that do not contain hazardous chemicals is environmentally and economically beneficial, recycling of materials containing POPs and other hazardous chemicals should be avoided to protect human health and the environment. A ban on recycling of c-decaBDE containing material may also promote innovative processes to detect POPs in waste and thus contribute to systems of labelling products through the whole life-cycle and in the end possibly stimulate to higher recycling rates because the recyclate is known not to contain hazardous chemicals. It could also positively affect the worker's conditions, particularly in developing countries e.g. by acting as a trigger for the formalization of the recycling industry (ILO, 2012).

2.4.2 Agriculture, including aquaculture and forestry

106. Elimination of c-decaBDE would benefit agriculture as well as human and wildlife health by ending further widespread dispersal of a POP substance to soil. Contamination of agricultural soil with BDE-209 is a global problem partly linked to the use of sewage sludge as a fertilizer (UNEP/POPS/POPRC.10/10/Add.2).As shown by Sellstrøm (2005) and de Wit (2005) levels of BDE-209 were 100-1000 fold higher at sites fertilized with sewage sludge compared to reference sites. When soil is amended with sludge, BDE-209 is transferred to biota, and can ultimately accumulate in organisms at the top of the food chain (UNEP/POPS/POPRC.10/10/Add.2). Applying sewage sludge to agricultural land is a way of managing sewage sludge while at the same time exploiting essential plant nutrients and organic matter in agriculture. However, as discussed above the practice contributes to the environmental releases of BDE-209. It may also contribute to human and ecological risks due to the occurrence of organic contaminants, such as BDE-209 in sludge. Accordingly, any measures to reduce the levels of BDE-209 in sewage sludge and/or measures to better control the use of sewage

sludge as a fertilizer, is likely to have a positive effect by reducing BDE-209 levels in agricultural products over time.

2.4.3 Biota (biodiversity)

107. A phase-out of c-decaBDE is essential to avoid an increase of levels in wildlife already at risk. Reported adverse effects raise concerns that c-decaBDE may cause effects at population- and ecosystem level, and ultimately have implications for biodiversity (see section 2.4.1 above UNEP/POPS/POPRC.10/10/Add.2). In addition to posing a threat to Arctic ecosystems and biodiversity, both alone or in combination with other POPs(UNEP/POPS/POPRC.10/10/Add.2, UNEP/POPS/POPRC.7/INF/16), it is of concern that c-decaBDE and other substances alone or in combination can delay development and metamorphosis in frogs at environmentally relevant concentrations (Shricks et al.,2006; Qin and Xia 2010) and alter the anatomy and function of the male frog vocal system (Ganser 2009). The IUCN Red List of Threatened Species™ has identified amphibians, and among them frogs, as being the most threatened vertebrate group assessed, with around 41% at risk of extinction and urges that immediate action must be taken to protect the remaining populations of amphibians across the world (IUCN 2014, see also Stuart et al. 2004). Extinctions and large-scale declines of amphibian species have been attributed to habitat loss, pollution, fires, climate change, disease and over-exploitation (IUCN, 2014; Hayes et al., 2010). Anthropogenic chemicals may contribute to the decline in amphibian populations by influencing the immune system/ immune response, larval development and growth, ability to avoid predation, reproductive success and survival rates (Carey and Bryant 1995, see also Hayes et al., 2010). The alterations in the male frog vocal system and the delayed metamorphosis/development induced by c-decaBDE exposure may have implications for lifetime fitness (mating success, predation etc.) and ultimately population recruitment (van Allen et al., 2010; Hayes et al., 2010). Thus, the adverse effects observed in frogs suggests that c-decaBDE can be one of the pollutants contributing to declines in global frog populations.

2.4.4 Economic aspects and social costs

108. Based on information such as price, accessibility and availability of different alternatives as well as information on regulatory measures and use in different countries, the socioeconomic costs of implementing a ban and/ or restriction on the use of c-decaBDE are considered small and outweighed by the benefits of an elimination/ regulation. An important factor as discussed in the EU restriction proposal is that although c-decaBDE is currently less expensive than the alternatives assessed, the difference in cost might gradually change in response to the increasing demand for alternatives (ECHA, 2014a).

109. The costs incurred by those manufacturers that still produce c-decaBDE depend on how a restriction/ban affects the production and market of chemical alternatives to c-decaBDE. It also depends on the technical costs associated with a transition from c-decaBDE to other alternatives at the manufacturing plants (ECHA, 2014a). However, c-decaBDE is known to be manufactured in only a few countries worldwide and a restriction/ban on the manufacture will therefore yields no cost (or impact) for the majority of countries worldwide, and will only affect a small number of manufacturers some of which already produce and sell c-decaBDE alternatives. Moreover, available information suggests alternatives can be manufactured in the same manufacturing plants/production lines as c-decaBDE without substantial technical modifications at the manufacturing plants. Thus, transition costs for the industry globally are assumed to be low.

110. The restriction could also affect the economy of c-decaBDE importers/vendors as well as down-stream industrial/professional users. However, most importers/vendors also import and sell other substances, including alternatives to c-decaBDE (ECHA, 2014a). Similarly, importers of c-decaBDE-containing articles may also continue to import articles with alternative FRs. Concerning down-stream industrial/professional users it is known that their capability to switch to alternatives may differ. Though most down-stream industrial/ professional users are able to transition to c-decaBDE alternatives without major additional costs, comments received from the aviation industry during a public consultation in the EU suggests that it may be difficult to immediately replace c-decaBDE in products used in aircrafts and defence hardware (ECHA 2014a). According to the aerospace industry, this is mainly due to technical challenges, costs and time related to the development, qualification, and certification of alternative materials for aircrafts due to stringent safety and technical performance requirements, and the complexity in the supply chain (ECHA, 2014a). Similar concerns have been raised by some automotive associations, which have requested exemptions for automotive vehicles currently in production and in spare parts.

111. A restriction on c-decaBDE might also have an impact on recycling, but the exact costs and benefits are hard to predict. At present around 20% of all plastic waste in the EU is recycled annually

on average, of which only a smaller fraction is FR plastic (RPA, 2014; ECHA, 2014a). In the U.S. EEE recycling is expected to increase in the future due to state law requirements, but in 2012 only 9 percent of the total plastic waste generated was recovered for recycling (U.S. EPA, 2014a,c). Listing c-decaBDE in the Stockholm Convention would mean that plastic fractions containing c-decaBDE above the low POP content limit value would not be recycled. In particular, recycling of waste electrical- and electronic plastic (WEEP) and plastic from end-of-life vehicles, which typically contains high levels of c-decaBDE, could be affected (e.g. IVM, 2013, see also Section 2.2.). This can lead to costs to society either in form of investment in costly equipment for sorting plastics waste and/or increase the need for manual labour, or in the form of temporarily increased resource use due to increased demand for virgin materials. However, based on the above mentioned studies, it appears that the economic impact on recycling may be limited given that c-decaBDE containing plastics only constitutes a smaller fraction of the relatively low amounts of plastics that are currently being recycled. In addition, several studies (including Kemi, 2012;Wäger et al., 2010; Stenvall et al., 2013; NCM, 2015b) highlights that hazardous substances negatively affects market prices for recycled plastics and is considered to be the major obstacle to recycling of WEEP and other types of plastic. Furthermore, several countries and regions have already banned or strictly regulated the use of c-decaBDE in EEE, meaning that recycling of WEEP in these countries would not necessarily be affected if c-decaBDE is listed in the Convention. For textiles, no or very limited recycling takes place in the EU and in the U.S. (ECHA, 2014a; U.S. EPA, 2014a; RPA, 2014). The assumed costs to society from not recycling this waste fraction are consequently low.

112. Besides the costs to industry, restricting the placing on the market of c-decaBDE may affect the employment in companies manufacturing the substance, as well as in actors in the supply chain including importers/exporters of c-decaBDE itself and c-decaBDE containing articles. Similarly, the employment in waste collection, sorting, recycling businesses may also be affected. The impact on employment depends e.g. on whether companies also produce and/or sell the alternatives substituting c-decaBDE. According to ECHA (2014) there are no reasons to assume differences in the labour inputs required in the production of c-decaBDE or alternative-based articles and products, and the negative impact to employment in one company (if any) should mainly be offset by positive impacts in other companies. In other words, the impacts on employment are mainly distributional and not a cost to the society as such. However, the redeployment of staff always includes some adjustment costs, e.g. related to temporary unemployment of workers when finding new jobs, although it is difficult to place a figure on these adjustment costs in practice (ECHA, 2014). Similar mechanisms will likely also affect employment in the waste- and recycling industry(see e.g. ILO, 2012;NCM, 2015b). Reduced profits will generally pull towards less employment, while potential new tasks, like sorting, may increase the employment needs. The net effect on employment in the recycling sector is therefore uncertain.

113. With further regard to social costs, a new report prepared by the Nordic Council of Ministers and recent scientific publications suggests that EDCs like c-decaBDE are a great economic burden to society (NCM 2014b; Bellanger et al.,2015; Hauser et al., 2015; Trasande et al., 2015; Legler et al., 2015). According to the report by the Nordic Council of Ministers, negative effects on male reproductive health caused by EDCs costs the EU countries at least somewhere between 59 and 1200 million euros per year in lost work capacity and higher health care costs. Similar findings are reported by Hauser et al. (2015), who stipulates the costs of male reproductive disorders and diseases in the EU to nearly 15 billion euros per year (15000 millions). Bellanger et al. (2015), which perhaps is the most relevant of these studies, suggests that PBDEs along with other EDCs contribute substantially to neurobehavioral deficits and disease in the EU, with a high probability of >150 billion euro costs/year. However, the publications by the Nordic Council of Ministers, Bellanger et al. (2015) and Hauser et al. (2015) centres on specific ECDs, disorders and diseases and the total costs to society attributable to EDCs are likely much higher than indicated by these studies alone. According to Trasande et al. (2015) median costs of only those EDCs which with the highest probability can be linked to disorders and diseases, is 157 billion euros annually i.e. 1.23% of EU gross domestic product. This finding is supported by a previous report prepared by the Health and Environment Alliance (HEAL) in the EU (HEAL, 2014). The report which includes costs related to treatment of human infertility, cryptorchidism, hypospadias, breast cancer, prostate cancer, ADHD, autism, overweight, obesity and diabetes, but not testicular cancer, stipulates that the total costs in the EU related to exposure to EDCs may be as high as 13–31 billion euros/year (HEAL, 2014).

114. Adding to the costs to the health- and welfare systems are costs relating to management of c-decaBDE containing waste and remediation of contaminated soil and sediment, which based on experience with other POPs such as PCB has shown both time consuming and costly.

115. According to the EU restriction proposal a restriction on production and use of c-decaBDE as suggested in the EUis considered a proportional measure to control the risks arising from its

production and use. More specifically, thecost-effectiveness is indicated to be in the same order of magnitude (or lower) as previous restrictions under REACH on mercury, a chemical that in previous EU assessments of mercury and phenyl mercury were considered to be of equivalent level of concern to persistent, bioaccumulative and toxic substances (PBTs) and to have long range transport properties (ECHA, 2014a).

2.4.5 Movement towards sustainable development

116. Elimination of c-decaBDE is consistent with sustainable development plans that seek to reduce emissions of toxic chemicals and that links chemical safety, sustainable development and poverty reduction. Environmentally sound management of "toxic chemicals" including waste is part of Agenda 21 and the Rio declaration on environment and development (UNCED, 1992a,b). It is also part of the Strategic Approach to International Chemical management (SAICM). The Global Plan of Action of SAICM contains specific measures to support risk reduction by promoting the use of safe and effective alternatives to chemicals, including non-chemical alternatives to organic chemicals that are highly toxic, persistent and bioaccumulative (UNEP, 2006).The Overarching Policy Strategy of SAICM includes POPs as a class of chemicals to be prioritized for halting production and use and substitution with safer substitutes.

117. For circular economy, design for recycling and labelling is important to improve the quality and quantity of recycled materials (NCM, 2014c). Applying techniques and systems that allow components containing hazardous chemicals to be sorted out and disposed of in an environmentally sound manner, will make waste management more sustainable, in particular with regards to material recovery, recycling and reuse (see Section 2.2).

118. In developing countries formalization of the e-waste recycling sector i.e. the integration of the informal sector into formal waste management, can present a way forward to create sustainable employment while at the same time reducing the negative environmental- and health impacts of recycling activities resulting from the release of POPs and other hazardous chemicals (ILO, 2012).

2.5 Other considerations

119. Listing c-decaBDE in Annex A without exemptions will involve control measures that are straight forward to communicate and therefore should be effective and suitable, even in countries that have limited chemical regulatory infrastructure. Information on alternatives is readily available, and can be easily communicated as needed. With regard to environmental monitoring and biomonitoring, c-decaBDE can be added to existing programmes for monitoring other POPs. Countries that lack the needed infrastructure to adequately monitor production and uses of c-decaBDE may require additional resources and infrastructure. However, recent developments in analytical chemistry allows c-decaBDE to be monitored and measured in parallel to other PBDEs, such as the tetra-, penta-, hexa- and heptaBDE congeners listed in the Convention, without substantial additional costs.

120. Parties to the Convention, for which any amendments have entered into force, have to meet the obligations under the Convention. To assist Parties in meeting their obligations, the Stockholm Convention has in the past developed inventory guidance's for listed POPs, the objective of which has been to provide step-by-step guidance to enable Parties to establish inventories of newly listed POPs and develop strategies/action plans (Decision SC-6/12, UNEP 2014a,b). The purpose of the inventory is to assist Parties in collecting national baseline data on the listed POPs, information that can be of use to national focal points for the Convention, the coordinator of the NIP review and update process, and task teams responsible for establishing the inventory. It will also be of interest to other stakeholders concerned with the elimination of listed Pops. In addition, also other types of guidance have been developed for example guidelines developed under Basel Convention.

121. Identifying which and whether articles/products contain a certain chemical can be a challenge. Recognizing these challenges, SAICM identified the global need for information on Chemicals in Products (CiP) throughout the whole lifecycle of the product, at the International Conference on the Chemical Management (SAICM/ICCM.2/15). A program to gain and exchange this kind of information globally was initiated. This included amongst others products such as electronics, textiles and toys which are known to contain c-decaBDE.

122. To develop effective strategies that can lead to the elimination of c-decaBDE, Parties need to acquire a sound understanding of their national situation concerning these chemicals. If c-decaBDE is listed in the Convention, the Conference of the Parties may therefore wish to task POPRC with updating the "Guidance for the inventory of polybrominated diphenyl ethers (PBDEs) listed under the Stockholm Convention on Persistent Organic Pollutants"to assist Parties to the Convention in meeting their obligations under the Convention and assisting them in their phase-out of c-decaBDE (UNEP 2014a).

3. Synthesis of information

3.1 Summary of risk profile information

123. At its 10th meeting in 2014 the POPs Review Committee adopted the risk profile and decided that the decabromodiphenyl ether component (BDE-209) of c-decaBDE is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted.

124. BDE-209 is highly persistent in soil and sediments, but it is also known to debrominate to lower brominated PBDEs in the environment and biota.Due to debromination, organisms are moreover co-exposed to a complex mixture of PBDEs, including the already listed POPs BDEs.

125. BDE-209 is an ubiquitous global contaminant that is detected in urban, rural and remote regions across the globe. In the Arctic and other remote regions BDE-209 is found in various environmental compartments including air, sediment, snow, ice and biota. Both oceanic and atmospheric processes contribute to the long-range environmental transport of BDE-209, but binding to atmospheric particles is believed to be the main mechanism.

126. Due to the extremely low water solubility of BDE-209 the most important exposure route in aquatic and terrestrial food webs is through the diet. Although some studies do not demonstrate BDE-209 bioaccumulation and trophic dilution has been observed (TMF<1), bioaccumulation has been reported for a number of aquatic and terrestrial organisms.The equivocality in the available bioaccumulation data of BDE-209 largely reflects species differences in uptake, metabolism and elimination.

127. C-decaBDE is widely detected in biota and high body burdens have been demonstrated in some species.BDE-209 can transfer from mother to off-spring and exposure takes place during early development. Maternal transfer to eggs and offspring has been reported in fish, amphibians, birds and reindeer.In humans, exposure to BDE-209 takes place in the early phases of development in utero via placental transfer and postnatally via mother's milk. In addition, infants and toddlers are reported to have higher body burdens of BDE-209 and other PBDEs than adults due to a higher exposure to dust.

128. There is evidence that BDE-209 can result in adverse effects to reproductive health and output in fish, earthworm, mouse and rats as well as developmental- and neurotoxic effects in amphibians, rodents and humans. Furthermore, there is a concern that BDE-209 and other PBDEs combined may cause developmental neurotoxicity in both humans and wildlife at environmentally relevant concentrations.Available toxicity data shows that BDE-209may act as an endocrine disruptor, and interfere with thyroid hormonehomeostasis in fish, amphibians, rat, mice and humans, and possibly with steroid hormone homeostasis. In combination,debromination and co-exposure to BDE-209 and other similarly acting PBDEs, as well as the high persistency of BDE-209 in sediments and soils, increase the likelihood for chronic long-term adverse effects.

3.2 Summary of risk management evaluation information

129. A positive impact on globally sustainable development is expected from elimination of c-decaBDE. However, if production, use and waste management of c-decaBDE are not controlled, the levels in the environment including humans and wild life will likely continue to increase, even in remote locations.

130. C-decaBDE is a synthetic substance with no known natural occurrence. Today c-decaBDE is manufactured only in a few countries globally. Many countries have already restricted or initiated voluntary programs to end the use of c-decaBDE. This has successfully led to use of alternative FRs, redesign or alternative methods to fulfil the FR requirements of the product. However, the environmental releases of c-decaBDE and its main constituent BDE-209are continuing in all regions investigated.

131. Although releases may also occur during production, c-decaBDE emissions are mainly attributed to releases from articles in use and waste. A global ban on production and use of c-decaBDE combined with proper waste management measures is therefore essential to achieve a future reduction in exposure of humans and the wildlife.

132. C-decaBDE has many applications and is used in many different sectors of society. It is used in EEE like computers and TVs, in wires and cables as well as in adhesives, sealants, coatings, inks and pipes. C-decaBDE is also extensively used in commercial textiles for public buildings, in textiles for domestic furniture and in the transportation sector. Globally up to about 90% of c-decaBDE ends up in plastics, primarily in electronics, while the remaining ends up in coated textiles, upholstered furniture and mattresses.

133. The automotive and aviation industry are in the process of phasing out c-decaBDE. However, some industry observers have raised a concern for service and replacement parts in articles already in use, as well as for vehicles/aircrafts currently in production under existing type certificates. The justification provided relates to technical and economic issues, and suggests a possible need for exemptions in the transportation sector. However, fire-safety requirements and certification schemes do not necessarily require the use of c-decaBDE or other FRs. In the case that replacement with another FR is necessary, chemical alternatives are available that can substitute c-decaBDE in most plastic and textile applications. Yet, in many cases, flame retardancy can also be achieved through the use of alternative techniques such as inherent flame-resistant material and use of different technical solutions i.e. barriers or complete redesign of the product. These alternative techniques can be used in a multitude of materials and applications, and are used in textiles, electronics, aircraft, and in other means of transportation.

134. The service-life of products containing c-decaBDE varies globally but an average of 10 years can be estimated, hence end-of-life products will enter the waste stream for many years and be a source to future emissions. According to the Convention (Article 6(1)(d)(ii)), waste containing c-decaBDE should be disposed in such a way that their POPs content is destroyed or otherwise disposed or irreversibly transformed of in an environmentally sound manner, thereby efficiently removing the emissions and related exposures to c-decaBDE in waste. Different techniques for handling POPs containing waste in an environmentally sound manner are available. Controlled incineration, in state of the art facilities with continuous monitoring, and strict compliance with Convention BAT/BEP guidelines, is one way to dispose of waste containing c-decaBDE and may allow energy recovery. Incineration at high temperatures is generally considered to effectively destroy POPs like c-decaBDE, with formation of small amounts dioxins and furans. Where destruction or irreversible transformation does not represent the environmentally preferred option, countries may allow such wastes to be disposed also by other environmentally sound methods e.g. in specially engineered landfills.

135. Sorting and separating waste fractions can be used to achieve more sustainable waste management, and separation techniques includes manual and automated sorting of waste components also those containing hazardous chemicals, such as brominated FRs.Advanced separation techniques are already in use in the waste management sectorand globally available. However, in developing countries, waste handling mostly occurs in the informal sector where modern industrial processes are not used, and sorting is conducted manually without the use of adequate protection and ventilation resulting in human and environmental exposures.In developing countries, integration of the informal sector into formal waste management, can present a way towards increased sustainability.

136. A small number of Parties have suggested a possible need for a recycling exemption. Yet, recycling of materials containing c-decaBDE will inevitably result in wider human and environmental contamination and dispersal of PBDEs. It should be avoided if the aim is to eliminate emissions and exposure to c-decaBDE. It was recently reported that plastic pellets from recycled material contaminated with c-decaBDE is subject to export and that this recyclate may end up in products where they can pose a hazard to human health.Recent studies have detected c-decaBDE in food-contact materials and in children's toys made from plastic pellets originating from recycled plastic. Moreover, the socioeconomic impacts of not allowing recycling of c-decaBDE above the POP limit value appear to be limited, an important reason being that recycling rates of c-decaBDE containing plastics and textiles are low.

3.3 Suggested risk management measures

137. The most efficient control measure to reduce the releases of c-decaBDE would be to list the decabromodiphenyl ether component (BDE-209) of c-decaBDE in Annex A without exemptions. Listing the decabromodiphenyl ether component (BDE-209) of c-decaBDE in Annex A would also mean that the provisions of Article 3 on export and import and of Article 6 on identification and sound disposal of stockpiles and waste would apply. According to the Annex F information submitted by Parties and Observers, no critical uses of c-decaBDE have been identified. In addition to the indicated need for a recycling exemption as discussed above, a few industry Observers have raised the possibility of exemptions in the transportation sector for service and replacement of parts in articles already in use. However, elimination or restrictions under Annex A or B in the Convention do not apply to articles manufactured or already in use before or on the date of entry into force of the relevant obligation with respect to a chemical. This suggests that a complete phase-out of c-decaBDE from all uses is possible and that exemptions for production and use are largely not critical.

4. Concluding statement

138. Having decided that the decabromodiphenyl ether component (BDE-209) of c-decaBDE, is likely, as a result of long-range environmental transport, to lead to significant adverse effects on human health and/or the environment such that global action is warranted;

139. Having prepared a risk management evaluation and considered the management options;

140. The Persistent Organic Pollutants Review Committee recommends, in accordance with paragraph 9 of Article 8 of the Convention, the Conference of the Parties to the Stockholm Convention to consider listing and specifying the related control measures of the decabromodiphenyl ether component (BDE-209) of c-decaBDE in Annex A.

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Persistent Organic Pollutants Review Committee
Eleventh meeting
Rome, 19–23 October 2015
Item 5 (b) (i) of the provisional agenda*

Technical work: consideration of draft risk profiles: dicofol

Draft risk profile: dicofol

Note by the Secretariat

I. Introduction

1. At its tenth meeting, the Persistent Organic Pollutants Review Committee adopted decision POPRC-10/3 on dicofol (see UNEP/POPS/POPRC.10/10, annex I). By paragraph 2 of that decision, the Committee decided to establish an intersessional working group to further review the proposal to list dicofol in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants (UNEP/POPS/POPRC.10/4) and to prepare a draft risk profile in accordance with Annex E to the Convention.

2. In accordance with decision POPRC-10/3 and the workplan for the preparation of a draft risk profile adopted by the Committee (UNEP/POPS/POPRC.10/10, annex III), the intersessional working group has prepared a draft risk profile, which is set out in the annex to the present note, without formal editing. A compilation of comments and responses relating to the draft risk profile is set out in document UNEP/POPS/POPRC.11/INF/8.

II. Proposed action

3. The Committee may wish:

(a) To adopt, with any amendments, the draft risk profile set out in the annex to the present note;

(b) To decide, in accordance with paragraph 7 of Article 8 of the Convention and on the basis of the risk profile, whether dicofol is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects, such that global action is warranted;

(c) To agree, depending on the decision taken under subparagraph (b) above:

(i) To invite all parties and observers to provide information pursuant to Annex F to the Convention, to establish an intersessional working group to develop a draft risk management evaluation and to agree on a workplan for completing that draft evaluation; or

(ii) To make the risk profile available to all parties and observers and set it aside.

* UNEP/POPS/POPRC.11/1.

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Annex

DICOFOL

DRAFT RISK PROFILE

Prepared by the intersessional working group on dicofol
Persistent Oranic Pollutants Review Committee

July 2015

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Executive summary

1. Dicofol is an organochlorine pesticide consisting of two isomers (p,p'-dicofol and o,p'-dicofol). Technical dicofol is composed of 80-85% p,p'-dicofol and 15-20% o,p'-dicofol with a reported variation range of DDT and other impurities. In several countries regulations exist with respect to the ΣDDT content of commercial dicofol. The FAO Specification 123/TC/S/F (1992) requires ΣDDT to be less than 0.1%. In Australia, Brazil, Canada, Japan, EU, and USA the limit is 0.1%. Dicofol has been sold from the mid-1950s as a miticidal pesticide and acaricide and has been used primarily in East and Southeast Asia, the Mediterranean coast, as well as in Northern and Central America. Dicofol is restricted or prohibited in many countries and usage has markedly decreased in the last decade (approximately 80% from the years 2000 to 2012).

2. Although laboratory data indicate that dicofol will not persist in water or sediment under neutral or alkaline conditions because of rapid hydrolysis at these pH values both isomers are stable under acidic conditions. Governmental assessment summaries showed a wide range of reported degradation half-lives in soil simulation tests, and some of them exceed 180 days. Field soil dissipation studies from Florida and California reported dissipation half-lives in the range of 7 to 113 days for dicofol. Experimental evidence suggests that abiotic as well as biotic degradation are dependent on the pH value of the receiving environmental compartment with longer degradation half-lives under acidic conditions. Several laboratory studies reported low mineralisation of dicofol.

3. The UN ECE Task Force on POPs under the Convention on Long-range Transboundary Air Pollution concluded that dicofol is persistent in acidic water and meets the persistency indicative numerical value of EB decision 1998/2. It can be anticipated that dicofol and/or its degradates (breakdown products) will persist longer in ecosystems (watersheds or soils) with acidic pH. Recent monitoring data have shown that dicofol is sufficiently persistent to be transported via riverine input to the open sea and, in one study, to remote regions. Therefore it is concluded that dicofol is otherwise sufficiently persistent to justify its consideration within the scope of this Convention.

4. Reported log K_{OW} values for dicofol range from 3.5 to 6.06. The bioconcentration potential of dicofol in aquatic organisms is confirmed by experimental data. The reported bioconcentration factors (BCFs) in bluegill sunfish and common carp range between 6,100 and 10,000. If steady state is considered, the BCF in bluegill sunfish is 25,000. In a full life cycle test with the fathead minnow the highest observed BCF value was 43,000. The high BCF values are reflected by slow elimination from fish tissue with a half-life of 33 days. Model estimates indicate that dicofol can accumulate in aquatic species with modelled BCFs >5,000 L/kg ww. Partitioning coefficients between octanol/water and octanol/air, indicators of potential bioaccumulation in terrestrial animals for the screening assessment of POPs, show that bioaccumulation in terrestrial species might occur if metabolism is not considered. For mammals half-lives of approximately 14 days are reported.

5. Degradation products are considered in the hazard profile of dicofol. Major degradates of dicofol with a higher persistence than dicofol include DCBP (dichlorobenzophenone), FW-152 (2,2-dichloro-1,1-bis(4-chlorophenyl)ethanol), DCBH (dichlorobenzhydrol), OH-DCBP (3-hydroxy-dichlorobenzophenone) and DCBA (dichlorobenzilic acid). DCBP, FW-152 and DCBH accumulated in a water/sediment study and can be considered as persistent in sediment. US EPA (2009) suggested a half-life of 313 days in soils for p,p'-dicofol plus major degradates and 32 days for p,p'-dicofol alone under slightly alkaline conditions. Modelled log K_{OW} values for the metabolites are below the screening value of 5. In absence of experimental data the estimated bioconcentration potential for the metabolite FW-152 is high. The acute LC50 toxicity values of p,p'-DCBP and p,p'-FW-152 for rainbow trout are >2.29 mg/L and 0.24 mg/L indicating for p,p'-FW-152 high toxicity to fish. The metabolite p,p'-DCBP has been shown to reveal potent antiandrogen activity *in vitro*.

6. The potential of dicofol for long-range transport (LRT) has been confirmed by screening information from physical chemical information, estimated degradation half-lives in air, the application of LRT models and [monitoring information from remote areas]. Atmospheric oxidation by hydroxyl radicals (OH) is a possible removal pathway for dicofol in the atmosphere. Depending on the OH radical concentrations half-lives are between 3.1 to 4.7 days.

7. LRT model results show that dicofol can be transported to remote regions with moderate efficacy and that it has a high modelled capacity for enrichment in the Arctic environment. [Though monitoring information from remote areas is limited, transport via air and seawater to the high Arctic demonstrates that dicofol can be detected far from sources due to LRT.] No measurements from biota in remote regions were found in the literature. Among other reasons difficulties to analyse dicofol properly could be involved in this observation.

8. In most of the recent environmental monitoring studies dicofol is not directly measured but dicofol application is indicated by the ratio of measured DDT (o,p'-DDT/p,p'-DDT), leading to the conclusion that dicofol is one source for current DDT pollution at least in regions of dicofol use. However, use of isomer ratios to determine whether dicofol is the source of environmental loads of DDTs should take into account environmental fate characteristics of the isomers.

9. Dicofol is classified for environmental hazards according to the Globally Harmonized System as very toxic to aquatic life (H400) and as very toxic to aquatic life with long lasting effects (H410). The lowest observed acute (96h-LC_{50}) and chronic (95d-NOEC) effects for fish were 0.053 and 0.0044 mg/L, respectively.

10. Dicofol has shown reproductive effects such as eggshell-thinning and feminization of male embryos in birds. Dicofol, DCBP and FW-152 have been detected in bird eggs indicating maternal transfer to offspring. Dicofol has been detected in a variety of environmental compartments and biota. With regard to the reported chronic and acute laboratory derived effect concentrations of dicofol (e.g. $NOEC_{fish}$ 0.0044 mg/L), the detected environmental concentrations in biota (up to 3.9 mg/kg) in crop areas (US EPA 2009) and water bodies in areas of dicofol use (up to 0.0036 mg/L, Bishnu et al. 2009) may indicate the potential for causing adverse effects in wildlife on a local and regional scale.

11. The metabolism of dicofol has been studied in laboratory rodents. After uptake dicofol is distributed preferentially to adipose tissue but also to muscles, lung, testes, liver, kidney, brain and heart and is eliminated mainly in the faeces. It has been shown that dicofol retains to a greater extent in adipose tissue of female rodents. In humans dicofol or its degradation products have been detect in breast milk, blood, colostrum and adipose tissue in the low ng/g and ng/ml range. (Haraguchi et al. 2009, Lessenger & Riley, 1991, Wang et al. 2011, Lucardo et al. 2013b, Wang et al. 2014). The maximum concentration of 559 ng/g was detected in adipose tissue (Wang et al. 2011).

12. Dicofol exhibits moderate acute toxicity in mammals; common signs of toxicity include decreased spontaneous motor activity, ataxia, passiveness, somnolence, prostration, and occasionally tremors. Chronic toxic effects concern the liver, thyroid, adrenals, brain, heart and testes. A number of recent in vitro studies demonstrate interaction with the endocrine system, protein binding activity, enzyme induction and interference with other chemicals. There is some evidence of neurotoxicity, immune effects, and reproductive effects. The assessment of dicofol by IARC (1998) found that no overall evaluation of the mutagenicity of dicofol could be made; there is limited evidence that it is carcinogenic to experimental animals and insufficient data to evaluate the carcinogenicity of dicofol to humans. Recent epidemiological studies have shown that dicofol exposure is associated with a greater incidence of prostate cancer. Certain epidemiological studies have noted associations between dicofol exposure and prostate cancer in men and leukaemia, Hodgkins disease and autism disorders in children. Limitations of these studies hinder definitive causal relationships. These epidemiological studies illustrate the concern that adverse effects associated with dicofol exposure might also occur in humans. Risk assessment for consumers has clearly demonstrated exceeding acceptable exposure limits by orders of magnitude (EFSA 2011).

13. [Based on persistence, bioconcentration, high aquatic toxicity, widespread occurrence in environmental compartments, together with the *in vitro* evidence of endocrine related effects of dicofol it is concluded that dicofol is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted.]

1. Introduction

14. In May, 2013 the European Community and its Member States submitted a proposal to list dicofol in Annex A, B and/or C of the Stockholm Convention (UNEP/POPS/POPRC.9/3), which was considered by the Persistent Organic Pollutants Review Committee (POPRC) at its ninth and tenth meetings held in October 2013 and 2014.

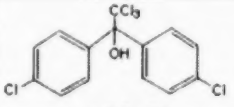
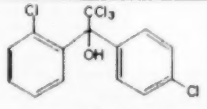
15. Dicofol is an organochlorine miticidal pesticide and acaricide and was introduced commercially in 1955 (WHO 1996). Dicofol acts as a mitochondrial electron transport inhibitor (Sanchez et al. 2010). The substance has been used primarily in East and Southeast Asia, the Mediterranean coast, as well as in Northern and Central America (Li et al. 2015). Intended uses of dicofol cover fruits, vegetables, ornamentals, field crops, cotton, Christmas tree plantations, and non-agricultural outdoor buildings and structures (US EPA 1998, Li et al. 2015). Concerning the mode of action in target organisms WHO (1996) reported that dicofol produces stimulation of axonal transmission of nerve signals, believed to be related to inhibition of ATPases in the central nervous system (CNS). The signs of toxicity are consistent with CNS depression. However, the Insecticide Resistance Action Committee (IRAC) has recently classified the mode of action for dicofol as

unknown or uncertain (IRAC 2008 cited in US EPA 2009). Sanchez et al. (2010) reported that dicofol acts as a mitochondrial electron transport inhibitor.

1.1 Chemical identity

16. Dicofol is comprised of two isomers: p,p'-dicofol and o,p'-dicofol. The technical product (95% pure) is a brown viscous oil and is composed of 80-85% p,p'-dicofol and 15-20% o,p'-dicofol with up to 18 reported impurities. The purer form is generally >95% dicofol which contains less than 0.1% DDT and related compounds (ΣDDT, i.e. DDT, DDE and DDD) (WHO 1996). Please see Table 1.1-1 for the chemical identity of dicofol.

Table 1.1-1. Chemical identity of dicofol

Common name IUPAC Chem. CAS chemical name	Dicofol 2,2,2-trichloro-1,1-bis(4-chlorophenyl)ethanol Benzenemethanol, 4-chloro-α-(4-chlorophenyl)-α-(trichloromethyl)- (CAS Registry)[1] 4-chloro-alpha-(4-chlorophenyl)-α-(trichloromethyl) benzene-methanol (WHO, 1996) 1,1-bis(4'-chlorophenyl)2,2,2-trichloroethanol (UNEP/POPS/POPRC.9/3)
Other names	1,1-bis(4-chlorophenyl)-2,2,2-trichloroethanol and 1-(2-chlorophenyl)-1-(4- chlorophenyl)-2,2,2-trichloroethanol ('p p'- and o,p'-isomer) (US EPA, 1998)
CAS registry number	115-32-2 (dicofol, p,p'-dicofol); 10606-46-9 (o,p'-dicofol
Trade name	1,1-bis(chlorophenyl)-2,2,2-trichloroethanol; 4-chloro-α-(4-chlorophenyl)-α-(trichloromethyl)-; Acarin; Benzenemethanol; Carbax; Cekudifol; CPCA; Decofol; Dicaron; Dichlorokelthane; Dicomite; Difol; DTMC; ENT 23648; FW293; Hilfol; Hilfol 18.5 EC; Kelthane; Kelthanethanol; Kelthane A; Kelthane (DOT); Kelthane Dust Base; Kelthane 35; Milbol; Mitigan; p,p-dicofol; NA2761 (DOT); NCI-C00486 (WHO, 1996).
Molecular formula	$C_{14}H_9Cl_5O$
Molecular weight	370.49
Structural formulas of the isomers	 p,p'-dicofol CAS No. 115-32-2  o,p'-dicofol CAS No. 10606-46-9

Physical and chemical properties

17. Dicofol has a water solubility around 1 mg/L and a low vapour pressure. The Henry's Law constant indicates low volatility from water and volatilization from moist soil surfaces is not expected to be an important fate process (HSDB 2015). However reported values differ considerably (cf. Table 1.1-2). Zhong et al. (2014) suggested that the low Henry's Law constant and the higher log Koa value of dicofol favour dicofol scavenging from atmosphere, and also dicofol partitioning in seawater. If released to air, a vapour pressure of 5.3×10^{-5} at 25 °C indicates that dicofol will exist in both the vapour and particulate phases in the atmosphere (HSDB 2015). Dicofol absorbs light >290 nm (HSDB 2015).

[1] http://www.cas.org/content/chemical-substances

Table 1.1-2. Selected physical and chemical properties

Property	Results	Source
Melting point, °C	77.5 78.5 - 79.5	Mackay et al. (2006) Tomlin (2001) in Rasenberg (2003)
Boiling point, °C	180 193 225	0.1 mmHg, Mackay et al. (2006) 360 mmHg, tech., Mackay et al. (2006) 665 Pa, UNEP/FAO/RC/CRC.2/14/Add.4
Density, g/cm³	1.45	Tomlin (1994) in Mackay et al. (2006)
Solubility in water, mg/L, at 25°C	0.8 1.32	Mackay et al. (2006) US EPA (2009)
Vapour Pressure, Pa, at 25°C	5.3×10^{-5} 2.5×10^{-4}	Mackay et al. (2006) PPDB (2012) in UNEP/POPS/POPRC.8/INF/13
Henry's Law Constant	5.66×10^{-5} Pa m³/mol (25°C) 2.45×10^{-2} Pa m³/mol (25°C) 1.44×10^{-7} atm m³/mol	Mackay et al. (2006) PPDB (2012) cited in UNEP/POPS/POPRC.8/INF/13, Saito et al. 1993 cited in Zhong et al. (2014) US EPA (1998)
Partition coefficient octanol/water (log Kow)	3.5 3.54 – 4.28 4.08 – 5.02 5.02 6.06	Kelly et al. (2007) Mackay et al. (2006) Rasenberg (2003) Li et al (2015, Supporting Information), measured value recommended by EPI SUITE TM US EPA (2009), measured value
Partition coefficient organic carbon/water (log Koc)	3.8	US EPA (2009)
Partition coefficient air/water (log Kaw)	-5.01	UNEP/POPS/POPRC.8/INF/13 (measured value recommended by EPI Suite v 4.0)
Partition coefficient air/octanol (log Koa)	8.9 9.3 10.03	Kelly et al. (2007) UNEP/POPS/POPRC.8/INF/13 (estimated value, EPI Suite v 4.0) Li et al (2015, Supporting Information)

Analytical method

18. The analysis of dicofol is affected by several difficulties, which have to be considered when evaluating the reliability of study results: it undergoes thermal breakdown during analysis, it can degrade to p,p'-dichlorobenzophenone (DCBP) and cannot be distinguished from other DCBP sources if only DCBP is detected and it degrades at high pH (EURL-SRM 2013). LC-MS/MS sensitivity for dicofol is very poor and the compound is thus typically analysed via GC (e.g. using ECD, MSD or MS/MS). GC-analysis, however, is very challenging due to the poor reproducibility of dicofol decomposition within the hot GC-inlet and the risk of complete decomposition. The most efficient way to eliminate all the above error-sources is the use of isotope-labelled dicofol (e.g. dicofol-D8) as internal standard (EURL-SRM 2013). Also the procedures of extraction and clean-up in which water and other solvents, as acetonitrile, are used can lead to degradation of dicofol (Spain, 2006). In most of the recent environmental monitoring studies dicofol is not directly measured but dicofol application is indicated by the ratio of measured DDT (o,p'-DDT/p,p'-DDT).

1.2 Conclusion of the Review Committee regarding Annex D information

19. The POPs Review Committee evaluated the proposal regarding dicofol (UNEP/POPS/POPRC.9/3) according to the requirements in Annex D of the Stockholm Convention at its ninth and tenth meeting in Rome. In Decision POPRC-10/3 the Committee reached the conclusion that dicofol fulfilled the screening criteria specified in Annex D. The Committee also decided to establish an ad-hoc working group to review the proposal further and prepare a draft risk profile in accordance with Annex E of the Convention

1.3 Data sources

20. The draft risk profile is based on the following data sources:

a) Proposal submitted by the European Community and its member States that are Parties to the Convention (UNEP/POPS/POPRC.9/3, UNEP/POPS/POPRC.7/INF/3), 2013.

b) Decision POPRC-10/3 of the POPs Review Committee, 2014.

c) Factsheet on dicofol, UNEP/POPS/POPRC.8/INF/13

[http://chm.pops.int/Convention/POPsReviewCommittee/POPRCMeetings/POPRC8/POPRC7WorkingDocuments/tabid/2801/Default.aspx, 2015-01-15]

d) Information submitted by Parties and observers according to Annex E of the Albania, Convention: China, Ecuador, Japan, Kenya, Mali, Netherlands, Serbia, Sweden, United States of America, International POPs Elimination Network (IPEN) and Pesticide Action Network (PAN)

This information is available on the Convention's website. [http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC10/POPRC10Followup/Dicofol(AnnexEinformation)/tabid/4293/Default.aspx, 2015-01-15].

e) International Programme on Chemical Safety, Dicofol, WHO/FAO Data Sheets on Pesticides No. 81 World Health Organization, Geneva, July 1996 [http://www.inchem.org/documents/pds/pds/pest81_e.htm, 2015-01-15]

f) Ospar Commission, 2002. Hazardous Substances Series, Dicofol. [http://www.ospar.org/v_publications/download.asp?v1=p00150, 2015-01-15]

g) US EPA, 1998. Reregistration Eligibility Decision (RED), Dicofol [http://envirocancer.cornell.edu/turf/pdf/dicofol_red.pdf, 2015-01-15]

h) US EPA, 2009. Risks of Dicofol Use to Federally Threatened California Red-legged Frog (*Rana aurora draytonii*) [http://www.epa.gov/espp/litstatus/effects/redleg-frog/dicofol/analysis.pdf, 2015-01-15]

In addition to these information sources, a literature search of public data bases was conducted that focused on recent scientific literature. The following databases were included: ECOTOXicology database, EU plant protection database, EFSA pesticides database, Pubmed, SYRAUSE Environmental Fate DataBase, OECD eChemPortal, TOXNET, The Carcinogenic Potency Database, NITE DataBase, GESTIS, WHOLIS Library and information networks for knowledge database, WHO, IPCS Inchem (International Programme of Chemical Safety), Biocatalysis/Biodegradation databases, PAN pesticide database, Google scientific search, U:search (University search, all e-journals).

1.4 Status of the chemical under international conventions

21. Dicofol is subject to a limited number of international treaties and conventions:

a) In December 2009 dicofol was proposed to be added to Annex I (prohibition of production and use) of the Aarhus Protocol on Persistent Organic Pollutants (POPs) under the Convention on Long-Range Transboundary Air Pollution. The POPs Task Force (except for one expert) concluded that Dicofol met the indicative numerical values of the Executive Body decision 1998/2. However no finalized action for dicofol under the LRTAP POPs Protocol was taken pending further consideration under the Stockholm Convention. In December 2013, the Executive Body of LRTAP decided to defer any discussion of dicofol until after COP7 of the Stockholm Convention in 2015[2] (Annex E information 2015 from USA).

b) The OSPAR Commission included dicofol in the List of Chemicals for Priority Action (by 2004). Further information can be found at http://www.ospar.org/

c) In 2012 the Chemical Review Committee (CRC) of the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for Certain Hazardous Chemicals and Pesticides in International Trade decided that for dicofol a notification from another PIC region is outstanding, therefore at this time dicofol has not been recommended for listing in Annex III of the Convention.

d) Since 2009 the specific exemptions for DDT (dichlorodiphenyltrichloroethane) listed in Annex B of the Stockholm Convention as intermediate in the production process of dicofol is outdated and no new registrations may be made with respect to such exemptions. However, use of DDT as a closed-system site-limited intermediate that is chemically transformed in the manufacture of other chemicals that, taking into consideration the criteria in paragraph 1 of Annex D, do not exhibit the characteristics of persistent organic pollutants is still allowed upon notification to the Secretariat (subject to a time limitation and a 5 yearly review for registered members).

2. Summary information relevant to the risk profile

2.1 Sources

2.1.1 Production, trade, stockpiles

22. Dicofol has been manufactured from technical DDT by hydroxylation of DDT (van de Plassche et al. 2003). In several countries regulations exist with respect to the ΣDDT content of commercial dicofol. The FAO Specification 123/TC/S/F (1992) requires ΣDDT to be less than 0.1%.

[2] http://www.unece.org/fileadmin/DAM/env/documents/2013/air/eb/ECE_EB.AIR_122_E.pdf

In Australia, Brazil, Canada, Japan, EU, and USA the limit is 0.1% (van de Plassche et al. 2003). Qiu et al. (2005) mentioned the legal requirement in China for DDT impurity to be no more than 0.5% of technical dicofol or no more than 0.1% of formulated dicofol by 2003. However, dicofol productions with impurities of ΣDDT above these standards are still available on the Chinese market even after that date. The authors reported an average contents of o,p'-DDT, p,p'-Cl-DDT, o,p'-DDE, and p,p'-DDT in 23 commercially available dicofol formulations of 11.4, 6.9, 4.4, and 1.7 %, respectively. This equals a ΣDDT content of 24.4%. Also Turgut (2009) investigated dicofol formulations on the Turkish market. The ΣDDT content of formulated dicofol was between 0.3% and 14.3%. A content of 3.5% ΣDDT has been reported in dicofol produced in India (van de Plassche et al. 2003).

23. Global production of dicofol between the year 2000 and 2007 was estimated to be 5,500 t/y (tonnes/year), whereas production in USA was estimated at 160 t/y for the years 1999 to 2004 (Hoferkamp et al. 2010). Spain produced approximately 1500 t/y (formulating was conducted in Italy), and use was reported to be 100–150 t in 2000 (van de Plassche et al. 2003). Until 2006 Spain was the major manufacturer and consumer (90 t in 2006) of dicofol in Europe (OSPAR, 2008).

24. The following notifications were made to the Stockholm Convention's register for closed site limited production/uses (UNEP, 2015[3]). In Brazil, dicofol was produced by Nortox (plant capacity was 200 kg/d), but production ceased in 2003 and 2004 for closed-site limited production. In India production and use was on the date of notification (10/27/2006) 150 t. Dicofol was produced in a closed system in batches. On the basis of the notification submitted to the Secretariat by India on 10 March 2014, the production and use of DDT as a closed-system site-limited intermediate in the production of dicofol has been extended until 15 May 2024 (UNEP/POPS/COP.7/4/Rev.1). In China production and use were on the date of notification (2/2/2005) 3,000-4,000 t. About 80% of DDT was used as an intermediate in the production of dicofol. There were 6 enterprises with the capability to produce dicofol (UNEP, 2015).

25. China has been a major producer of technical DDT and dicofol, with >85% of the global technical DDT production occurring here, which amounted to approximately 97,000 t between 1988 and 2002. Over half of this amount (approximately 54,000 t) was used to manufacture dicofol (40,000 t) (Qiu et al. 2005). In China, the enterprises registered to produce technical dicofol and its formulations were distributed in 13 provinces and municipalities. Currently, there is only one technical dicofol producer in China (Annex E information, China, 2015). In 2013, this producer stopped producing technical dicofol. In 2014, it shut down its production line for technical dicofol. By a letter dated 28 February 2014, China notified the Secretariat that as of May 2014 it had withdrawn the use of DDT as a closed-system site-limited intermediate starting from June 2014 (UNEP/POPS/COP.7/4/Rev.1-Corr.1).

26. In India, the Indian state-owned enterprise, Hindustan Insecticides Ltd, has a production capacity for dicofol of 150 t/y (company homepage[4]) and still manufactures dicofol with an average annual production output of approximately 50 t (Li et al. 2015). No data on current production could be found in literature regarding other potential current producers, e.g. Dow AgroSciences and Adama Agricultural Solutions Ltd (formerly Makhteshim Agan Industries Ltd)

27. In 2011 US EPA published an order for the voluntary cancellation of dicofol at the request of the registrant (Makhteshim Agan of North America, Inc). Existing stocks provision allowed the registrant to reformulate it into end-use products and sell it until 2013. Sale and distribution by others was allowed until 2013. A final rule revoking most dicofol residue tolerances was issued in 2012. Import tolerances for tea were maintained pending future decision making (Annex E information, USA, 2015).

2.1.2 Uses

28. Dicofol is used as miticidal pesticide and acaricide in many countries around the world and reported to be applied to food, feed, and cash crops including apple, citrus, lichi, longan, pear, leafy vegetables, tea, and cotton (Li et al. 2015). It is also used on ornamentals such as orchids. In Senegal, dicofol is used on onion, watermelon, potato and pimento crops (Jepson et al. 2014). In Mexico, there are 17 registrations for dicofol, which is authorized for the application on aubergine, chilli, strawberry, lime, apple, orange, pear, watermelon, mandarin, grapefruit, vine, citrus fruits, ornamental shrubs, ornamental plants and nursery gardens (comment from Mexico, May 2015, to the POPRC dicofol draft risk profile). In China, dicofol is not permitted on vegetables or fruit (Wang et al. 2015). It is reported to be restricted or prohibited in most developed countries. In Canada use has not been permitted since

[3] http://chm.pops.int/Implementation/Exemptions/RegisterofSpecificExemptions/tabid/1133/

[4] http://www.hil.gov.in/DICOFOL%20.html

2011 and in USA will not be after 2016 (Li et al. 2015; Annex E information, USA, 2015). Dicofol is banned in Benin, Côte d'Ivoire, the European Union, Guinea, Iraq, Japan, Mauritania, Oman, Romania, Saudi Arabia, and Switzerland (Annex E information, 2015 and comments from Iraq and Côte d'Ivoire, May 2015, to the POPRC dicofol draft risk profile).

29. Li et al. (2015) estimated, based on a combination of literature surveys, field surveys and personal communications, a total of 28,200 t (tonnes) of dicofol used globally in a 13 year period from 2000 to 2012, mainly in Asia (21,719 t), followed by North America (1,817 t), Europe (1,745 t), Latin America (1,538), Africa (1,434 t) and Oceania (13 t) The estimated use by continent in 2012 was for Asia 619 t (mainly in China 530 t and India 43 t), North America (USA) 33 t, Latin America 38 t, Africa 36 t, and Oceania around 1 t. Over the period 2000 to 2012, 76.8% of the usage was estimated in Asia and there mainly in China (69.1% of total usage). However, between 2000 and 2012 the estimated dicofol usage decreased by 75% in China (from 2,013 t to 530 t), 69% in India (from 145 t to 43 t) and 90% in the USA (from 324 t to 33 t) with most use occurring in California and Florida. The decrease of estimated global use from 2000 (3,350 t) to 2012 (730 t) was approximately 80%. Average application rates were 1.3 kg/ha, 0.44 kg/ha and 0.31-0.45 kg/ha in the USA, Europe and China, respectively (Li et al. 2015).

30. In Europe dicofol usage decreased from 317 t to 32 t between 2000 and 2009. According to estimated emission data published by van der Gon et al. (2007), the major consuming countries in 2000 were Spain, Italy, Turkey, Romania, and France. In EU countries, the use of dicofol for plant protection products expired by 2010 at the latest according to Commission Decision 2008/764/EC[5]. In addition all non-agricultural uses are prohibited according to the Biocidal Products Regulation No (EC) 528/2012[6].

31. Notice No. 11 of 1997 issued by Ministry of Agriculture of China banned the use of dicofol on tea plants. Ministerial Announcement of Agriculture No. 199 of 2002 restressed the ban of dicofol on tea plants. At present, registered use of dicofol in China is to prevent *Tetranychus cinnbarinus*, *Tetranychus viennensis (Zacher)* and *Phyllocoptruta oleivora (Ashmead)* on cotton, citrus and apple trees (Annex E information, China). The market share of dicofol in China's acaricide market has declined from 27% (in 1999) to less than 8% after 2008 (Li et al. 2015).

32. In summary the data provided by Li et al. (2015), together with other above mentioned literature sources, plausibly indicate a decreasing trend of global dicofol usage, which probably is continued after the observed study period (2000-2012). Therefore, it can be estimated, that the current global dicofol use is well below 1,000 t/y.

2.1.3 Releases to the environment

33. Principal releases to the environment can occur from the production process, professional or private use and the resulting waste. Li et al. (2015) estimated via BETR-Global Modelling the realistic global contribution of dicofol and concluded that, of the estimated 28,200 t used between 2000 and 2012, 731 t remain in the environment. They also estimated that 1.9 t of dicofol has been deposited in the Arctic, and 2.2 t in the Antarctic as a result of LRT.

34. Dicofol is produced in a closed system but releases can result from improper production practices. Li et al. (2014) described DDT, dioxin and furan releases from a closed system dicofol production process in China. The annual amounts of ΣDDT and p,p'-DDT directly released to the environment via the use of dicofol were estimated as 9,480 kg and 1,080 kg, respectively. From the PCDD/F distribution patterns, it is suggested that the major pathway for PCDD/F formation involves precursor synthesis during the production of dicofol in the closed-system process, which is estimated to result in an annual release to the environment of 0.17 g I-TEQ (toxicity equivalent value) from this particular company (Li et al. 2014).

2.2 Environmental fate

2.2.1 Persistence

Abiotic degradation

35. Both dicofol isomers are susceptible to aqueous hydrolysis and the hydrolysis degradation rate is pH dependant. o,p'-Dicofol hydrolysed with half-lives of 47 days at pH 5, 8 hours at pH 7, and 9 minutes at pH 9. p,p'-Dicofol hydrolysed with half-lives of 85 days at pH 5, 64 hours at pH 7, and 26 minutes at pH 9 at 25°C (IUCLID cited in Rasenberg, 2003; US EPA 1998). The major degradate in the studies, the o,p'- and p,p'-isomer of dichlorobenzophenone (DCBP), appeared to resist further

[5] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32008D0764

[6] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L:2012:167:TOC

degradation (no quantification was provided in US EPA, 1998). Other metabolites for p,p'-dicofol were isolated but not identified (US EPA 1998). According to Boethling et al. (2009) the potential for the formation of more persistent degradation products must also be assessed for all POPs.

36. At a pH of 5, the half-life of dicofol's main p,p'-isomer was 85 days, fulfilling the cut-off value of 60 days for persistence in water (UNEP/POPS/POPRC.10/10). Approximately 680 (14%) out of 4,837 watersheds i.e. lakes and rivers from northern European countries (DK, GB, IE, FI, NO, SE, EE) have a minimum pH value of ≤6 and 139 (3%) watersheds displayed a pH ≤5. The data were extracted from the European Environment Agency (2015) Waterbase databank[7]. Pienitz et al. (2004), Hawes et al. (2002) and Michelutti et al. (2002) reported in addition to neutral and alkaline pH values also acidic pH values in several Arctic lakes and ponds. Black-water rivers found in several areas around the world (Australia, Amazonia, Europe, Indonesia, the Orinoco basin and the northern and southern areas of the United States) typically have a pH of around 5 (Alkhatib and Jennerjahn 2007).

37. Experimental data on aqueous photolysis of dicofol at pH 5 showed that o,p'-dicofol photolysis with a DT50 of 14.8 days and p,p'-dicofol photodegraded with a half-life of 92.5 days (US EPA, 1998). If corrected for the control samples the DT50 values for o,p'-dicofol and p,p'dicofol are 27.5 and 244 days, respectively (US EPA, 2009). US EPA (2009) reported soil photolysis half-lives of 56 and 21 days for o,p and p,p'-dicofol, respectively. Photolytic half-lives of 30 days for both isomers were cited in Spain (2006). However the photolysis studies lacked information with regard to the light spectrum and TLC chromatograms. p,p'-DDD and DCBH were detected with 4.5% and 20% applied radioactivity respectively (Spain, 2006). US EPA (2009) concluded that photodegradation is not expected to be significant route of dissipation of dicofol in the environment.

38. The estimated atmospheric half-life for dicofol based on reaction with hydroxyl (OH) radicals is 3.1 days, using the default atmospheric hydroxyl radical concentration of 1.5×10^6 molecules/cm^3 during sunlight hours in AOPWIN, EPISUITE v4.11TM computer program[8]. Using a lower hydroxyl radical concentration of 5×10^5 molecules/cm^3, which is generally used as a daily (24-hour) average in relatively unpolluted air in the EU (EC 2003), the atmospheric half-live is 4.7 days. It should be noted that hydroxyl radical reaction rates vary spatially and temporally with average daily sunlight, and 5×10^5 molecules/cm^3 may not be typical of northern latitudes since hydroxyl radical concentrations decline with latitude. Moreover AOPWIN estimates the gas-phase reaction rate for the reaction between OH radicals and the chemical at 25°C. However based on the physical chemical properties (cf section 1.1) dicofol can exist in air in the gas and particulate phase. (HSDB, 2015) reported for dicofol light absorption at wavelengths >290 nm which suggests that photolysis may be an important degradation process in the atmosphere (Chen et al. 1984 cited in HSDB, 2015). Rena et al. (2011) studied the theoretical photodegradation mechanisms of dicofol by density functional theory calculations. The authors found that OH radicals attacking the C7-C8 bond and the addition of OH to the C12 atom of dicofol are favourable pathways. Besides one dominant reaction product $(C_6H_4Cl)_2CO$ a precursor for forming polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/Fs), C_6H_4ClOH(4-CP) was identified.

Biotic degradation

39. In a ready biodegradability test, conducted according to the OECD 301C Test Guideline dicofol (at a concentration of 100 mg/L which is above the water solubility of 1 mg/L), reached 0% of its theoretical BOD (biological oxygen demand) in 4 weeks using an activated sludge inoculum at 30 mg/L (Japanese NITE database, 2015)[9].

40. The fate and behaviour of dicofol during wastewater treatment has been assessed by Oliveira et al. (2012). The authors specifically investigated the biodegradation of dicofol during aerobic wastewater treatment and anaerobic sludge biodigestion using ^{14}C labelled dicofol. Residues of dicofol, and the breakdown product DCBP, were quantified, but the recovery rate for dicofol in wastewater was only about 60%. After seven days of the aerobic process 55%-60% of the applied radioactivity (AR) was associated with the activated sludge (14% dicofol, 41% 'p,p'-DCBP and 45% to the wastewater (5% AR dicofol, 40% AR unknown metabolites). After aerobic treatment only 0.1% AR of dicofol was mineralised. After 18 days in the anaerobic process, only 3% of the dicofol and 5% of p,p'-DCBP was detected in the sludge with 70% of remaining radioactivity in the sludge associated with other metabolites. This study, therefore, suggests that dicofol can be degraded (in the system studied) to other compounds, but not mineralised. However, sewage treatment plants are not

[7] http://www.eea.europa.eu/data-and-maps/data/waterbase-rivers-10

[8] http://www.epa.gov/opptintr/exposure/pubs/episuite.htm

[9] http://www.safe.nite.go.jp/jcheck/detail.action?request_locale=en&cno=115-32-2&mno=4-0226 (Reports: Dicofol (The results of the investigation))

expected to be primary receiving compartments for dicofol; this route of elimination may not be the most relevant to the use-profile for dicofol.

41. In a laboratory water/sediment test with two different water/sediment systems (pH >7) DT50 values in the whole sediment/water system were between 7 and 13 hours for p,p'-dicofol and less than 2 hours for o,p'-dicofol. Isomer specific accumulation in sediments of major metabolites at the end of the experiment after 100 days occurred for p,p'-DCBP (22% AR), p,p'-DCBA (dichlorobenzilic acid, 10% AR) and o,p'-DCBH (dichlorobenzhydrol, 40% AR). Other major metabolites >10% AR detected in the studies were: o,p'-DCBP, p,p'-DCBH, p,p'-FW-152 (2,2-dichloro-1,1-bis (4-chlorophenyl)ethanol) and o,p-DCBA (UNEP/POPS/POPRC.8/INF/13, Spain, 2006). A new study with water/sediments at pH <7 has been required for the assessment of the fate of dicofol in the aquatic environment (Spain, 2006 in UNEP/POPS/POPRC.8/INF/13). Rasenberg (2003) indicated half-lives in sediment for DCBP, DCBH and DCBA in the range of 7 to 13 days, 197 to 429 days and 24 to 174 days, respectively. However no study details or study source has been quoted. According to Annex E submission (2015) from USA, dicofol is expected to partition to sediment based on log Kow of 6.06 and a Koc of 7,060 mL/g. US EPA (2009) stated that anaerobic soil metabolism studies (pH value 7.9) indicate that dicofol will degrade relatively rapidly in sediment with a half-life less than 30 days. Xia (2008) reported enhanced disappearance of dicofol by water hyacinth in a laboratory study.

42. In an aerobic soil study under laboratory conditions (20-25°C), o,p'-dicofol was degraded more rapidly than p, p'-dicofol. The data showed that the rate of degradation was fastest in soils with higher pH. Reported DT50 values in the two soils (pH >7) ranged from 9 to 204 days for the two isomers. In the other two European soils (pH <7), no degradation was observed under the study conditions. Mineralisation was low (Spain, 2006 cited in UNEP/POPS/POPRC.8/INF/13). According to the results of degradation studies in soil and the results of the hydrolysis studies, the degradation of dicofol is pH dependant (Spain, 2006). Many areas especially in northern Europe have a soil pH<7 (Böhner et al. 2008). pH in soils globally can be found in IGBP-DIS (1998). In the Annex E submission (2015) from Sweden referring to an ecotoxicological evaluation in 1988, it was concluded that dicofol has a slow degradation.

43. US EPA (2009) indicated for lab soil simulation studies that o,p'-dicofol degraded with a half-life of 8.5 days in a loam soil and the p,p'-isomer degraded with a half-life of 32 days in a silt loam soil. Major metabolites for the p,p'-isomer were p,p'-FW-152, p,p'-DCBP, and 3-hydroxy-4, 4'-dichlorobenzophenone (3-OH-p,p'-DCBP). Volatile residues were 21-22% and <4% of the applied and unextractable residues were 10-15% and 57-61% of the applied after 12 months for the p,p'- and o,p'-dicofol isomer, respectivley (US EPA 1998). Parent plus major degradation products of concern (including the o,p'- and p,p'-isomers of DCBP, FW-152, DCBH, OH-DCBP) degraded with a half-life of 104.5 days and 313 days in two soil metabolism studies for o,p'-dicofol and p,p'-dicofol, respectively (US EPA 2009).

44. US EPA (1998) stated that in ecological monitoring studies conducted in Florida and California, dicofol dissipated from the soil surface with a half-life ranging from 58 to 113 days. In a dissipation study on cotton in California half of dicofol residues dissipated in less than 7 days. In another dissipation study on strawberries in California dissipation DT50s of 22 days for o,p'-dicofol and 72 days for p,p'-dicofol were measured. Kumari and Duhan (2011) carried out a field trial in India to assess the persistence of residues of dicofol on cotton and in soil after spraying. Residues dissipated almost completely from soil in 60 days (dissipation half-life of 9 days). However the soil was extracted with ammonia and the detection method did not account for analytical losses. Dicofol residues were detected in cotton lint and seed. No degradation products were measured or suggested by the authors. A field trial at 26°C and pH 5.9 reported a (dissipation) half-life of 40 to 50 days (study author Hofmann 1986 Annex E information, 2015, Sweden). However no DT50 value could be calculated from this study according to Spain (2006). EFSA (2014) pointed out that there are a number of difficulties in the determination of a reliable degradation rate parameter from field studies e.g. the initial decline of applied substance can be more rapid followed by a slower rate of decline, loss of the substance due to volatilisation or leaching, uptake by plants, run-off etc. However, translocation processes did not play a part in the loss or degradation rate of dicofol in the Florida and California studies.

45. US EPA (2009) indicated a conservative estimate for persistence of dicofol (considering the parent and major degradates) of as high as 313 days and noted the lack of adequate information to estimate persistence of dicofol degradates in the environment. Based on the available environmental fate data, US EPA determined that dicofol is not expected to persist in the environment, with half-lives less than 90 days in soil, depending upon the specific environmental conditions.

Monitoring data

46. Weaver et al. (2012) investigated organochlorine residues in surface soils from the Namoi Valley, Australia. The study aimed to quantify historical residues in soils. Dicofol was measured and detected by a certified Government analytical laboratory in one Vertisol soil sample at 18 ng/g. The pH of this soil was 6.9 ($CaCl_2$) and the detected level was attributed to a historic use (T. Weaver, personal communication, March, 2015). Dicofol was also measured in deeper layers in dated sediment cores from lake Saint André in northern France by Sabatier and co-workers. Measured residues traced back to the 1940s with highest levels in the 1970s, 1992, and 2000. Though no half-lives were calculated the data indicate that dicofol can persistent in this environment for several decades (Sabatier et al. 2014). Zhong et al. (2014) measured high dicofol levels in surface sediment samples from the coastal and offshore regions of the Bohai and Yellow seas. The presence of concentrations of dicofol at river estuaries, sea water (pH >7) and sea sediments suggests that dicofol is sufficiently persistent to be distributed to the sea. Mean concentrations of dicofol near the Yangtze River and Yellow River estuaries were seven times higher than those at other sampling sites (Zhong et al. 2014) indicating higher inputs closer to the estuaries. Though data for remote regions are very limited, dicofol has been detected in the Arctic environment in seawater and air (one study: Zhong et al. 2012) suggesting sufficient persistence to be transported to higher latitudes (reported levels from source regions and higher latitudes are reported in section 2.3.1).

Summary on persistency

47. Experimental evidence suggests that abiotic as well as biotic degradation of dicofol are dependant on the pH value of the receiving environmental compartment with longer degradation half-lives under acidic conditions. o,p'-Dicofol and p,p'-dicofol are stable under acidic conditions in hydrolyses studies. According to the available laboratory studies dicofol will degrade in aquatic compartments with a pH >7. Experimental primary degradation half-lives for dicofol in soil are equivocal, but according to field studies (California and Florida) dicofol is not persistent in soils. However no field studies in colder climates are available. A conservative estimate for persistence of o,p'- and p,p'-dicofol (considering the parent and major degradates of concern) of as high as 104.5 and 313 days in soil (from laboratory studies) was reported. Recent monitoring data have shown that dicofol is sufficiently persistent to be transported via riverine input to the open sea and to be detected in deep sediment layers dated back to 1940s. One study has measured dicofol in remote regions. Modelled data indicate that the persistence of dicofol in the environment is lower or comparable to benchmark substances and known POPs.

2.2.2 Bioaccumulation

Screening assessment based on physical-chemical properties

48. The reported log Kow values for the p,p'- and o,p'-isomers of dicofol span a wide range from 3.5 to 6.6, respectively (see section 1.1). A maximum measured log Kow value of 6.06 was used for modelling estimates by US EPA (2009). The following log Kow values for dicofol are reported by Li et al. (2015): 5.02 (measured value recommend by KOWWIN in EPI suite), 4.18 (logarithmic mean of measured values 4.08-4.28) for p,p'-dicofol and 4.40 (logarithmic mean of measured values 4.32-4.34) for o,p'-dicofol. For dicofol metabolites (DCBP, FW-152, DCBH and OH-DCBP), estimated log Kow values ranging from 3.96 to 4.89 (EPISuite v.4.0) are cited in US EPA (2009). These values indicate a potential for bioconcentration in aquatic organisms for dicofol as well as for its degradation products, although most of them are below the screening trigger of 5 of the Stockholm Convention.

49. The octanol/air partition coefficient (Koa) is mentioned as an indicator of potential bioaccumulation in terrestrial animals for the screening assessment of POPs (UNEP/POPS/POPRC.3/INF/8, 2007). Kelly et al. (2007) proposed that the biomagnification of dicofol in the terrestrial food chain is particularly relevant, because it has a high log Koa. The proposed log Koa values for dicofol are between 8.9 and 10.03 (Kelly et al. 2007; Li et al., 2015, Supporting Information), respectively. Based on a log Kow range of 3.5 to 6.06 and a log Koa range of 8.9 to 10.02, a high bioaccumulation potential in both air-breathing organisms and aquatic organisms can be expected (log Kow higher than 2 and a log Koa higher than 5 according to ECHA 2008). For the degradation products log Koa values were estimated with KOAWIN EPISuite v.4.1. Estimated log Koa values were 8.799 for DCBP, 12.07 for FW-152, and 10.4 for DCBH. Log Kow values und log Koa values for the metabolites are in the range that indicate a high bioaccumulation potential in terrestrial organism according to Kelly et al. (2007) and ECHA (2008).

Bioconcentration and bioaccumulation studies in aquatic organisms

50. In a 28-day laboratory BCF study with bluegill sunfish (*Lepomis macrochirus*) exposed to p,p'-dicofol, a BCF of 10,000 was observed in whole fish (steady state was not reached), the estimated steady-state BCF for dicofol was 25,000 US EPA (2009). In this study, parent dicofol represented >94% of the radioactivity measured after the 28-day exposure, suggesting that metabolism of dicofol was minimal in fish. FW-152 and OH-DCBH were detected in tissue samples (each at 4.7% AR) according to US EPA (2009) and UNEP/FAO/RC/CRC.2/14/Add.4 in Annex E information, Netherlands (2015).

51. UNEP/POPS/POPRC.8/INF/13 cited the same BCF of 25,000 for dicofol (p,p'-isomer) in fish with a slow clearance time and a estimated depuration rate (CT_{50}) of 110 days. No further information is given on the fish species used or BCF calculation details.

52. In an early life stage test with the aquatic invertebrate, *Hyalella azteca* and the fathead minnow (*Pimephales promelas*), mean 28-day BCF values of 10,000 (±3000) and 3,700 (±800), respectively, were observed. As the duration of this study was insufficient to allow the test organisms to reach steady-state, it is expected that if the duration had been extended, observed BCF values would have increased, according to US EPA (2009). In another study quoted in US EPA (2009), a full life cycle test (flow-through conditions) with the fathead minnow, the highest observed BCF value was 43,000, which was observed in F_0 females after 296 days of exposure to dicofol. The BCFs (based on total ^{14}C activity; range of 11,000 to 43,000) from this study indicated that dicofol tends to concentrate in the tissues of fish at all growth stages (Spain, 2006).

53. Studies according to the OECD 305 Test Guideline resulted in BCF values of 8,200 and 6,100, obtained for common carp exposed to 0.1 and 1 µg/L (Japanese NITE database, 2015[10]). A recent bioaccumulation test based on the use of zebrafish eleutheroembryos as an alternative to adult-individuals indicate that the BCF was highest for dicofol compared to chlorpyrifos and atrazine. Zebrafish eleutheroembryos (72 h after hatch) were exposed to 0.1 and 1 µg/L dicofol for a period of 48 hours. Steady state was not reached. The log BCF was 3.9 (=7,943 L/kg) calculated with two toxicokinetic models assuming steady state (El-Amrani et al. 2012). Based on analytical challenges to measure dicofol accumulated residues might also include breakdown products in the above cited studies.

Toxicokinetic and metabolism studies

54. In bluegill sunfish elimination was slow with minimal metabolism. The estimated depuration half-life was 33 days (US EPA 1998, US EPA 2009). Several toxicokinetic studies on rats and mice indicate a gender specific elimination rate with half-lives less than 8 days for single exposure. In an ADME (adsorption, distribution, metabolism, excretion) study in rats dicofol distributed preferentially to adipose tissue and was eliminated mainly in the faeces. Essentially the entire dicofol dose was excreted within 8 days (IPCS Inchem 1992). For repeated exposure elimination half-lives were estimated to be 6-14 days for dicofol (Steigerwalt et al. 1984b cited in IPCS Inchem 1992).

Assessment of bioconcentration and biomagnification models and monitoring data

55. Based on governmental assessment reports (US EPA 1998, US EPA 2009, Spain 2006) and the conducted literature search no empirical information on bioaccumulation, biomagnification and trophic magnification in food webs is available for dicofol.

56. However, Malik et al. (2011) examined the potential persistence and bioaccumulation for dicofol across three heronries based on the rivers Chenab, Ravi and the Rawal Lake Reservoir in the Punjab region of Pakistan. Samples of surface sediment (n=15, to a depth of 3-8 cm) along with prey item (e.g. insects, toads, fishes) (n=150) and egret eggs (n=30, one egg from each nest) from within the heronries were collected during the summer months of 2007. Sediment mean concentration from Chenab and Ravi were 12.5±18.4 and 11.3±16.2 ng/g, respectively. The key finding his that, in all cases, the greatest concentrations of dicofol from the three locations were found within egg samples (10±21.3, 38.4±50.2 and 48.3±53.3 ng/g, mean values) compared to prey (not detected, 21.6±30.6 ng/g and 10.3±14.5 ng/g, mean values), suggesting biomagnification in all three heronries. However results were not lipid corrected, so the values may not fully explain if there was in fact accumulation.

[10] http://www.safe.nite.go.jp/jcheck/detail.action?request_locale=en&cno=115-32-2&mno=4-0226 (Reports Dicofol (The results of the investigation))

57. Estimated BCF values for dicofol with the KABAM model[11] ranged from about 28,000 L/kg for filter feeders to about 55,000 L/kg for phytoplankton (USA, Annex E submission, 2015). Estimates of FW-152 residues in fish were highest among the model results for metabolites (US EPA 2009).

58. QSAR (Quantitative Structure Activity Relationship) estimates for the log BCF values of the metabolites p,p'-DCBP, p,p'-DCBP, p,p'-FW-152, o,p'-FW-152 and p,p'-DCBH, p,p'-DCBH was calculated using VEGA[12]. VEGA is an open source platform, that contains three BCF tools including one read across model. Read across, in this case, means that unknown values (in this case log BCF) of a target compound(s) are estimated based on the known values for structurally related substances. For FW-152 isomers a log BCF of 3.77 (5,904 L/kg) was calculated with the BCF read across model.

59. Kelly et al. (2007) calculated (assuming a log Kow of 3.5) high biomagnification factors (BMFs) in terrestrial species ranging from 6.1 in reptiles to 76 in humans. However, metabolic transformation can reduce or eliminate the anticipated biomagnification potential, but only if the metabolic transformation rate is sufficiently high, in which cases, the bioaccumulating behaviour of resulting metabolites should also be consider.

Summary on bioaccumulation

60. Dicofol has a high bioconcentration potential as demonstrated by experimental derived BCF values in fish that range from 6,100 to 43,000 and an experimental calculated depuration half-life of 33 days in bluegill sunfish. Model calculation indicates high biomagnification factors for terrestrial species, if metabolic transformation was not considered. For dicofol metabolites log Kow values are below 5, however log Koa values indicate that a high bioaccumulation potential might occur based on this screening information (without the consideration of metabolism). In addition a QSAR model calculation identified a high bioconcentration potential for FW-152.

2.2.3 Potential for long-range environmental transport

Screening of physical-chemical properties

61. Under Annex D, an atmospheric half-life >2 days is recognized as a criterion for long-range transport potential (LRTP). Calculated half-lives in air at 25°C in the gas phase for dicofol are between 3.1 and 4.7 days (cf. section 2.2.1). Taking into account the much lower temperatures of the troposphere, the half-life of dicofol under real situations is likely to be longer. The degradation rate constant is temperature dependant (cf. Aktinson 1989). Based on the vapour pressure combined with the propensity of the compound to sorb to particles (see section 1.1), dicofol is expected to partition between the gas and particle phases in the atmosphere. The average half-life time for particles is estimated to be about 3.5 - 10 days and the average life time for particles is estimated to be about 5 - 15 days (Atkinson et al. cited in Rasenberg 2003).

LRT model predictions

62. Several models have been developed for estimating the LRT potential of POP candidates. The MSCE (Meteorological Synthesizing Centre East) POP model (Vulykh et al. 2005), a multicompartment chemistry transport model, uses a benchmark approach to overcome model dependency of numerical values. Benzo(a)pyrene (B[a]P) is a listed POP in the UN ECE POPs Protocol and was selected as a benchmark substance because of its high travel distance of approximately 2,400 km, its environmental half-life of approximately 75 days. For their model, they assume dicofol half-lives of 3, 30 and 60 days in air, water and soil, respectively. The model predicts an atmospheric travel distance (TD; the distance after which the concentration has fallen beneath 1/1000 of that at the source) of 1,650 km. The estimated environmental half life of dicofol was 20 days. The ranking of dicofol and B[a]P with respect to environmental half life shows that dicofol is less persistent than B[a]P. According to the model calculations of TD, LRT of dicofol is slightly less than that of B[a]P.

63. US EPA (2009) estimated the overall persistence (Pov) and LRTP of dicofol and its breakdown products with the OECD "Pov and LRTP Screening Tool". Pov metrics combines estimates of single-media half-lives with the multi-media partitioning of a chemical and do not rely on the single-media half-lives as persistence criteria. Pov takes into account the environmental media a chemical is likely to partition to, and weigh the single-media half-lives with the chemical's fractions in the individual media (Wegmann, 2009). The characteristic travel distance (CTD) represents the potential of a chemical to be transported over long distances in air or water (distance at which the concentration of chemical decrease to 37% due to transport). The transfer efficiency (TE) is a

[11] http://www.epa.gov/oppefed1/models/water/kabam/kabam_user_guide_appendix_d.html

[12] http://www.vega-qsar.eu/index.php

dimensionless metric of potential for atmospheric transport and deposition of parent compound in terrestrial and aquatic environments of a remote region. The OECD Tool requires estimated degradation half lives in soil, water and air, and log Kaw and log Kow as chemical-specific input parameters. According to US EPA (2009) there are considerable uncertainties in the environmental fate properties (input values) of the selected chemicals under consideration, and the results indicate that dicofol and its breakdown products have Pov lower and LRTP properties similar to those of several known POPs. P,p'-DDT, aldrin and endrin display a Pov of 1010, 225 and 1556 days, a CTD of 2530, 206 and 515 km and a TE of 5.17, 0.003 and 0.04%. The Pov, CTD and TE for o,p'-dicofol and p,p'-dicofol were 37 and 138 days, 2142 and 1467 km and 9.45 and 3.39%, respectively. For the metabolites model predictions for DCBP, FW-152 and DCBH were 172, 516 and 108 days for Pov, 1381, 504 and 238 km for CTD and 2.24, 2.15 and 0.66 % for TE.

64. The most recent LRT potential was assessed by Li et al. (2015) with the Globo-POP model. Li et al. (2015) summarized that dicofol, relative to other Arctic contaminants, exhibits a moderate 'absolute Arctic Contamination Potential' ($eACP^{air}_{10}$) and the highest 'relative Arctic Contamination Potential' ($mACP^{air}_{10}$), indicating that it can be transported from source locations to the Arctic environment with moderate efficiency, that its persistence is more influenced by temperature with cold temperatures in the Arctic favouring slow degradation and relative enrichment, whereas warm temperatures near the equator favour fast degradation. Based on the simulated total dicofol mass that resides in the Arctic surface media (M_{Arctic}) after a decade of continuous emission, $eACP^{air}_{10}$ is defined as the percentage of M_{Arctic} in the cumulative global emission. $mACP^{air}_{10}$ is defined as the percentage of M_{Arctic} in the total dicofol mass remaining in the entire global environment by end of the tenth year. Dicofol has a similar eACPair10 (0.06%) compared with HBCD (0.05%) or aldrin (0.04%). The $mACP^{air}_{10}$ for dicofol (3.7%) was higher than lindane (3.39%) and DDT (2-3%). The rate of decline of dicofol concentration in the Arctic lags behind the rate of decline in global dicofol usage, indicating modelled accumulation in the Arctic as a result of slowed temperature-dependent degradation according to the model results (Li et al. 2015).

Confirmation based on measurements in remote areas

65. Zhong et al. (2012) provides evidence of dicofol in environmental media remote from sources, based on a study carried out on surface seawater and marine boundary layer air data collected during a cruise from the East China Sea (33.2°N) to the high Arctic (84.5°N). Dicofol was detected in air (predominantly gas phase) and in seawater (cf. section 2.3).

Summary of for long-range environmental transport

66. Dicofol has a calculated half-live between 3.1 and 4.7 days that is a screening indicator for LRT. Model results showed that dicofol can be transported to remote regions and displayed LRT properties similar to those of several known POPs. Limited evidence of dicofol in environmental media from remote sources (one study) is available.

2.3 Exposure

2.3.1 Environmental monitoring data

Remote areas

67. In a large scale study from East Asia to the high Arctic Ocean, dicofol was abundant found along with the already listed POP α-endosulfan and detected in average levels of 14 ± 29(SD) pg/m^3 in air and 9 ± 23(SD) pg/L seawater (Zhong et al. 2012). Concentrations decreased from ~25 pg/m^3 and 87 pg/L at 35°N to 0.9-2.5 pg/m^3 and <0.2-2 pg/L at 66-80°N latitude in air and seawater, respectively. The authors used the data to calculate air-water fugacity ratios at each of the sampling locations which provide information on the likely net direction of chemical transfer. It was suggested that air was the dominant mode of transport, with dicofol being carried from original source and deposited into surface water at all points along the cruise, although deposition rates were highest close to potential source regions. Zhong et al. (2012) performed a polar extract of the samples and a GC injection technique (pulsed splitless) that helps to prevent thermal breakdown of dicofol. Moreover they used an internal dicofol standard and an isotope labelled surrogate (but not dicofol-D8). Therefore, and supported by discussions with experts and clarification by the authors (G. Zhong, personal communication, April, 2015), the study results seem to be plausible, based on the applied analytical method.

68. Levels of dicofol and DCBP (could not be separated analytically) in Canadian archipelago Arctic air were ~2 pg/m^3 during ArcticNet cruises in 2011-2013 (L. Jantunen, Environment Canada, personal communication, 2015). Hoferkamp et al. (2010) were unable to find any results for dicofol in Arctic environmental media. Muir and de Wit (2010) stated that there were no direct measurements of dicofol in the Arctic. Among other reasons the analytical problems of dicofol could be involved in this

observation. Kucklick (J. Kucklick, personal communication, November, 2013) mentioned for example the difficulties of detecting dicofol in seal samples.

Regional and local scale

69. In air and seawater of the Bohai and Yellow Seas, China, dicofol was frequently detected. Gas phase atmospheric concentrations averaged 3.8±2.3 pg/m^3, whilst particulate concentrations were lower averaging 0.68 pg/m^3 (Zhong et al. 2014). Dissolved seawater concentrations averaged 63±65 pg/L with highest concentrations up to approximately 240 pg/L. Zhong et al. (2015) analysed dicofol in 72 surface sediment samples from the coastal and offshore regions of the Bohai and Yellow seas, which border on regions of high pesticides consumption and production and are exposed to huge amounts of runoff and sediment load of several rivers. Dicofol was detected in 60% of the samples and dominated the concentration profile with 90% of the reported concentrations greater than 100 pg/g dw, an average concentration of 1,300±2,500 pg/g dw and a highest concentration of 18,000 pg/g dw. Concentrations generally reflected those measured in air and water with higher values closer to estuaries indicating on-going riverine sources including inputs from local areas of production.

70. In sediments in California's Central Valley, dicofol was found in 75% of the 28 tested samples up to 250 ng/g (Weston et al. 2013). In an earlier publication (Wang et al. 2010) dicofol was detected in five out of 12 sediment samples from California's Central Valley with reported concentrations of 36±207 (mean±SD) ng/g dw. In lower regions of Yangtze River, Tang et al. (2013) detected dicofol levels of 0.46±1.38 (mean±SD) ng/g dw in the sediment, whereas the dicofol levels in the surface water where below the detection limit (<0.28 ng/L).

71. In a national survey in France, dicofol was not detected in any of 154 sediment sampling points (Vulliet et al., 2014). This observation is in line with the findings of Thomas et al. (2012), where dicofol was not detected in freshwater fish and sediments from fish ponds in north-eastern France.

72. In a vineyard watershed in France, Sabatier et al. (2014) reconstructed the long term levels of dicofol in lake sediment. Concentrations showed peaks in 1970, 1992 and 2000 reaching fluxes of approximately 4.5, 8.0, 6.0 ng/cm^2/y, respectively. In transboundary aquifers in North-eastern Greece, dicofol was detected in one out of 37 wells above the EC drinking water quality standards limit of 0.1 µg/L, at a level of 0.153 µg/L (Vryzas et al. 2012). Papadakis et al. (2015) examined 416 water samples from six rivers and ten lakes in the main cultivation areas of Greece (collected from Sep. 1999 to Feb. 2001) and calculated annual average concentrations for dicofol in surface water bodies of 0.01µg/L, which exceeds the annual average for EU Environmental Quality Standard for dicofol (0.0013 µg/L) according to Directive 2013/39/EC.[13]

73. Bishnu et al. (2009) detected dicofol in the water bodies in tea gardens in the Doars region of West Bengal, India, in April, at a mean level of 3.6 (range 0.9–5.8) µg/L. Domagalski (1996, cited in US EPA 2009) reported for an analysis of water samples from San Joaquin River (California) and its tributaries that all samples collected between March and June 1993 were below detection limits but in June to September 33 samples were found above the detection limit (0.05 µg/L) with max concentrations of 2.5 µg/L. From 1990-2006, 618 samples from surface waters were analysed for dicofol in the California Department of Pesticide Regulation (CDPR) database. Of these, dicofol was detected in 11 (1.8%) of the samples, with a maximum concentration of 0.27 µg/L (US EPA 2009). The Pesticides in Ground Water Data Base (US EPA 1992, cited in US EPA 2009) showed no detections of dicofol in limited sampling in several States, including California (1634 wells sampled between 1979 and 1991).

74. Syed and Malik (2011) detected dicofol in surrounding surface soils of an industrial site in Pakistan in 69% of 36 samples at a mean level of 10.75 ng/g, although it is not quite clear to what extent these levels originate from industrial production processes (including waste dumping) or from agricultural use in this area. .

75. Weaver et al. (2012) found dicofol in surface soil (one sample was analysed for dicofol measuring 18 µg/kg) from the Namoi Valley, Australia. Dicofol was measured at up to 53.2 pg/m^3 in urban air in Spain (Coscolla et al. 2011).

76. Dicofol levels (highest mean concentrations) in biota in crop areas with historical dicofol use have been reported by the US EPA (2009) for small mammals (up to 1.4 µg/g, Florida), terrestrial invertebrates (up to 3.9 µg/g, California) and reptiles/amphibians (up to 3.8 µg/g, Florida). In non-crop areas the highest mean concentrations of dicofol were 0.3 µg/g for small mammals, 0.76 µg/g for terrestrial invertebrates, 0.38 µg/g for reptiles/amphibians, 0.9 µg/g in birds and 0.26 µg/g for fish. In

[13] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32013L0039

New York dicofol was detected in earthworms at a level of 1-2 µg/g. In eggs collected from thirteen avian species in California, Florida and New York, the yearly mean levels for dicofol, p,p'-FW 152 and p,p'-DCBP ranged from 0.003 - 0.46, 0.002 - 0.218, and 0.004 – 0.165 µg/g, respectively (US EPA 2009). The dicofol levels found by Malik et al. (2011) in eggs of cattle egret, prey samples and sediment in Pakistan are described in section 2.2.2. Dicofol was also frequently detected in liver samples from six species of predatory birds of the Canary Island, Spain with concentrations ranging from 0.001 to 0.0095 µg/g ww (Luzardo et al. 2014).

77. In animal feed samples in India, dicofol was found at mean concentration ranging from 0.03 to 0.34 µg/g (Nag & Raikwar 2011). Dicofol has been shown to accumulate in cows' fat and milk (Shaffer 1987, unpublished): 0.5 µg/g of p,p'-dicofol in the fat after 29 days of 10 µg/g in food. In mutton bird in New Zealand, dicofol was not found in any of the analysed samples (Bekhit et al. 2011). However, if DCPB is not reported, dicofol measurements may likely underestimated due to the breakdown of dicofol to DCPB during sample analysis.

DDT and related compounds from dicofol production and use

78. Dicofol can contain DDT and related compounds depending on the manufacturing method (UNEP/POP/POPRC.10/4). The ratio of o,p'-DDT/p,p'-DDT can indicate dicofol as source of DDT (use of dicofol or DDT). For ΣDDT originating from technical DDT a ratio of 0.2 to 0.3 is typical, whereas a ratio of 1.3 or higher (mean ratio 7) indicates technical dicofol as source (Qiu et al. 2005; Qiu and Zhu 2010). The following discussion below focuses on data pertaining to the use of technical dicofol.

79. The ratio of o,p'-/ p,p'-DDT has been used in literature to distinguish between DDT and dicofol as source of ΣDDT. But to use isomer ratios for the estimation of their emission source, the environmental fate of the two isomers should also be taken into consideration (e.g. differing volatility from soil to air, stability in soil, air water fluxes and bioaccumulation). However, Ricking and Schwarzbauer (2012) claim that the potential to follow the environmental fate of ΣDDT via isomer composition has not been realized accurately so far and, consequently, has not been well established in the field of environmental chemistry. In case of the ratio of o,p'-/ p,p'-DDT the 4.7-fold higher water solubility and 7.5-fold higher vapour pressure of the o,p'-than the p,p'-isomer (Ricking and Schwarzbauer, 2012) have to be considered. Regarding the half-life of the isomers further studies are needed (Qiu et al. 2005). A faster metabolization of o,p'-DDT in the environment is reported by Martin et al. (1993, in Li et al. 2006), whereas in Bidleman et al. (2013) a preferential degradation of p,p'-DDT versus o,p'-DDT is mentioned. Hence, source correlations far away from areas of dicofol use have to be interpreted cautiously. On the other hand the fact that dicofol is one source of current DDT pollution cannot be neglected.

80. Dicofol as source for ΣDDT was suggested by the authors for sediments from Yangtze River Estuary and the adjacent East China (Zhou et al. 2014a), for surface sediments in Pakistan (Syed et al. 2014), in an Eurasian Eagle owl population from south-eastern Spain (Gomez-Ramirez et al. 2012) and mussels collected from a Spanish estuary (Suarez et al. 2013).

81. In more remote areas ΣDDT possibly originating from dicofol exposure was found in air in a mountain of the Tibetan Plateau of China (Zhu et al. 2014); in soil, lichen, conifer needles and bark of the Southeast Tibetan Plateau (Yang et al. 2013) and potentially in the Kara Sea (Russian Arctic) possibly originating from the Ob and Yenisei Rivers (Carroll et al. 2008). The analysis of an extensive database of organochlorine (OC) pesticide concentrations measured at the Norwegian Arctic monitoring station at Svalbard revealed an increasing trend in o,p'-DDT/p,p'-DDT ratios in the Arctic atmosphere, which may indicate a shift from use of technical DDT to dicofol (Becker et al. 2012).

82. In contrast to the findings above, there are also studies existing, which state that the DDT residue ratios are indicating technical DDT as the source rather than dicofol (Qu et al. 2015, Yu et al. 2014, Ding et al. 2009). Monitoring results from the Portuguese coast showed no predominance of o,p'-DDT and therefore Mizukawa et al. (2013) estimated no dicofol induced DDT pollution for this region. The ratios of o,p'-DDT/p,p'-DDT in marine fish from the South China Sea were <1, suggesting that dicofol was unlikely the source of DDT (Hao et al. 2014).

2.3.2 Human Exposure

83. Dicofol has been measured in breast milk in China (geometric mean = 9.63 ng/g lipid; max = 64 ng/g), Korea (mean =1.87 ng/g, max =2.96 ng/g) and Japan (mean = 0.32 ng/g; max = 2.65 ng/g) (Fujii et al. 2011); and in adipose tissue in 75-95% of people tested in 3 regions of China, with a maximum value of 559 ng/g and means of 9.06, 2.91, and 4.82 ng/g (Wang et al. 2011). Elevated ratios of o,p'-DDT to p,p'-DDT in breast milk in China is suggested to result from dicofol exposure (Haraguchi et al. 2009, Wang et al. 2014). In Spain dicofol was detected in 27.8% of 18 colostrum

samples with concentrations ranging between 0.12 and 0.59 µg/L (median 0.35 µg/L), but was not detected in 13 major human milk samples from the Canary Islands (Luzardo et al. 2013b).

84. Chen et al (2014) analysed 10 human milk samples collected from anonymous donors in 2010-2011, 10 cow milk samples and 10 baby formula samples purchased from local stores in USA. In all analysed samples, p,p-dicofol, o,p-DDE, p,p-DDE, chlorpyrifos and hexachlorbenzene were found. Detected p,p-dicofol concentrations ranged between 0.033 and 0.230 ng/ml (median 0.091 ng/ml) in cow milk, 0.029 and 1.115 ng/ml (median 0.109 ng/ml) in human milk, and 0.029 and 0.096 ng/ml (median 0.047 ng/ml) in baby formula.

85. The concentration of organochlorine residues was measured in pasteurized milk from Mato Grosso do Sul, Brazil. Of the 100 composite samples analysed, dicofol was detected in 14% in the range of 2.75–9.61ng/g lipid with a mean concentrations of 5.11ng/g lipid (Avancini et al. 2013).

86. Luzardo et al. (2013a) investigated the presence of organochlorines in locally produced eggs from different production sites (conventional, free-run and organic; n=12 each) collected in 2012 from supermarkets and stores for organic food in the Canary Islands (Spain). All analysed samples contained low but quantifiable levels of organochlorine pesticides. Dicofol was present in 75% of eggs from conventional production (range: n.d.-8.42 ng/g; median: 0.93 ng/g), in 41.7% of eggs from free-run production (n.d.-1.08; 0.57), and in 58.3% of eggs from organic production (n.d.-2.31; 1.07).

87. Wang et al. (2013) examined pesticide residues including 33 different pesticides in market vegetables (n=285) in Shaanxi Province of China by GC. Dicofol was detected in 1.05% of the samples in both green pepper and chives samples. In Bangladesh 210 samples of 8 types of vegetables collected in 2009-2012 were analysed for 19 agricultural pesticides. Dicofol was detected only in one sample (cucumber) at a concentration of 0.14 mg/kg (Chowdhury et al. 2013). Yan et al. (2014) detected dicofol in four of nine celery samples in local markets of Baoding, Korea at levels of 3.6, 2.5, 2.5, and 3.4 ng/g.

88. According to European Food Safety Authority (EFSA) 2011 appropriate analytical methods for the detection of dicofol were lacking, which may result in underreporting of residues. They suggested measurements e.g. in plant commodities: o,p'-dicofol, p,p'-dicofol and their corresponding DCBP, for milk from ruminants sum of dicofol (sum of o,p'- and p,p'-isomers) and FW-152. A new analytical method was published from the European laboratories for residues of pesticides in 2013 (EURL-SRM, 2013). Therefore, data reported before 2011 might be less sensitive and negative results in these studies might not be an indication of lack of exposure. In processed commodities the major degradation product seemed to be the corresponding DCBP, but formation of chloroform under boiling and sterilization conditions cannot be excluded (EFSA 2011).

89. The 2013 European Union report on pesticide residues in food of EFSA documented dicofol detections in 0.15% of the samples. Highest mean concentrations have been found in mandarins with 0.02 mg/kg. Highest concentrations were detected in strawberries with 0.04 mg/kg (EFSA 2015).

90. Lozowicka (2015) investigated 696 samples of Polish apples in the period of 2005–2013 (182 samples for pesticides). Dicofol was detected in 4 samples and the median of the four residue levels (above the LOQ) was 300% higher than the maximum allowable residue level. The highest measured value was 0.156 mg/kg (EFSA 2013).

Consumer Exposure and Risk Assessment

91. In 2011 EFSA reviewed maximum residue levels for dicofol (EFSA 2011). As dicofol is no longer registered in the EU, only the Codex limits (CXLs) were considered in the calculations of the consumer exposure. Assuming the toxicological reference values, the highest chronic exposure was calculated for the Dutch children, representing 1379% of the acceptable daily intake (ADI of 0.002 mg/kg bw). Exceedances of the acute reference dose (ARfD of 0.15 mg/kg bw) were also identified for the existing CXLs in oranges, grapefruits, mandarins, table grapes, lemons and peaches. Excluding CXLs for these commodities and those not sufficiently supported by data from the calculation, the highest chronic exposure still represented 258.1% of the ADI for the French population. When only considering the CXL for tea (50 mg/kg), the highest chronic exposure declined to 95.7% of the ADI for Irish adults; the highest acute exposure is then calculated for tea, representing 30.7% of the ARfD. It has been stated that CXLs considered for consumer risk assessment were actually based on European uses of dicofol that are no longer authorised, except for tea, for which the notifier made a specific request (EFSA 2011).

Summary of human exposure

92. Due to the chemical instability of dicofol in solution as well as limitations in analytical methods reported dicofol measurement values may result in underreporting. However, dicofol and/or

its metabolites have been detected in milk, baby formula, eggs, fruits, vegetables, human breast milk, colostrum and blood. Exposure calculations based on Codex limits revealed up to 13.9 fold exceedances of the TDI for the population group with the highest exposure.

2.4 Hazard assessment for endpoints of concern

Adverse effects on aquatic organisms

93. Dicofol is highly toxic to aquatic animals as defined in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNEP/POPS/POPRC.10/10). It is classified as aquatic acute and chronic category 1 in the European Union's regulation on the classification, labelling and packing of substances and mixtures (Regulation (EC) No. 1272/2008). According to OSPAR (2002) the lowest LC50 for fish is 0.053 mg/L; the lowest value for crustaceans is 0.08 mg/L, and the no observed effect concentration (NOEC) in a 300-d chronic exposure of fish was 0.0045 mg/L. US EPA (1998) cites effects on the reproductive physiology of the fathead minnow from concentrations as low as 0.0055 mg/L.

94. Dicofol acute toxicity ranges from very highly toxic to highly toxic to freshwater fish and invertebrates under acute exposure conditions (Annex E information, USA, 2015). The LC_{50} values for seven species of fish range from approximately 0.05 to 0.6 mg/L, whereas for invertebrates (*Daphnia magna*) an EC_{50} of 0.14 mg/L was observed (US EPA, 2009). Chronic exposure to freshwater animals resulted in adverse effects on growth and reproduction in multiple fish species with a no observed adverse effect concentration (NOAEC) of approximately 0.004 mg/L (95d-NOEC= 0.0044 mg/L) and on survival in amphipod with a NOAEC of 0.019 mg/L (US EPA 2009). For rotifers the 11d-NOEC for growth rate was 0.2 mg/L, and for the maximum population density in correlation with the food density 0.1 mg/L and 0.2 mg/L for the lower and the higher food amount, respectively (Xu et al. 2014).

95. In a comparative analysis between fish and mice (Grisolia 2002) erythrocyte micronuclei assays, injection of the dicofol formulation Kelthane 480 CE induced a significant increased micronucleus frequency in the fish *Tilapia rendalli* (from 25 mg/kg), but not in mice (up to 200 mg/kg).

96. Regarding the acute toxicity values of dicofol metabolites, the 96h-LC_{50} values for rainbow trout are >2.29 and 0.24 mg/L for p,p'-DCBP, and p,p'-FW-152, respectively (Spain, 2006). The 96h-LC_{50} of p,p'-FW-152 is in the range of those reported for dicofol.

Adverse effects on terrestrial organisms

97. In terrestrial species, dicofol induced chronic effects including parental systemic and reproductive effects in rat (NOAEL 0.4 mg/kg bw/day). Dicofol is non-lethal to the adult honey bee on an acute exposure basis (LD50 > 0.05 mg/bee) (US EPA 2009). However, task-dependent behavioural effects on learning have been observed in honeybees when exposed to sublethal concentrations of dicofol (Stone et al. 1997). For earthworms (*Eisenia foetida)* a LC50 of >354 mg/kg dw was reported (UNEP/POPS/POPRC.8/INF/13). A two-generation study of reproductive and morphoiogical effects of o,p'-dicofol on captive American kestrels by MacLellan et al. (1996) showed for females exposed to 5 and 20 mg/kg bw significantly thinner egg shells at 20 mg/kg of o,p'-dicofol. Male embryos from females dosed with 5 and 20 mg/kg bw of o,p'-dicofol had gonads that were significantly ($p<0.05$) different from those of control chicks, indicating feminization by the presence of primordial germ cells. Wiemeyer et al. (2001) reported that the lowest observed dietary effect concentration for eggshell thinning was 3 mg/kg ww diet and that the NOAEC was 1 mg/kg ww diet for a dicofol formulation without any measureable ΣDDT. US EPA (2009) also reported the LOAEC of 3 mg/kg diet and NOAEC of 1 mg/kg diet) based on decreased egg shell thickness. According to the OSPAR document on dicofol (OSPAR 2002), the pattern and magnitude of dicofol (0.0334 mg/g, <0.1% ΣDDT) on eggshell thinning was similar to that observed with p,p'-DDE. Schwarzbach et al. (1988, cited in OSPAR, 2002), showed that dicofol was not metabolized to DDE in birds and therefore concluded that the adverse effect (egg shells became progressively thinner with increasing time of exposure) was caused by dicofol itself.

98. In embryonic livers of *Gallus domesticus*, a formulation of dicofol (Colonel-S® 18.5%) applied as solution in which the eggs were immersed for 60 min on day 0 and 4 of incubation at concentrations of 250, 500 and 1000 mg/L induced severe biochemical and histological alterations (e.g. extensive cell degeneration and necrosis with enlarged blood sinusoids, cytoplasmic vacuolization, and leucocyte infiltrations with congestion or dilation of central vein, decrease in the levels of total protein, glycogen, and glutathione content and an increase in alkaline phosphatase activity) (Bhaskar et al. 2014). The survival rate of chick embryo was reduced and the number of malformations was exhibited by a formulation of dicofol (18.5% EC) applied at concentrations of 250,

500 and 1000 mg/L (Nitu et al., 2012). In both studies concentrations were selected in correlation to the recommended application rate (500 mg/L) for the products used in plant protection practise and indicate adverse effects of short time exposure of eggs to dicofol, although it is unlikely that this exposure scenario (immersion of 60 min in a dicofol solution) will appear during direct overspray in field. In-ovo exposure to dicofol resulted in damage of Japanese quail reproduction, mainly through eggshell thinning in dosages of 0.0003, 0.001 and 0.003 mg/g of egg (Kamata et al. 2010).

99. According to the US EPA (2009) risk assessment of dicofol use, risks to aquatic invertebrates, fish, aquatic-phase amphibians, terrestrial-phase amphibians and mammals were identified. A risk due to indirect effect based on habitat effects was identified for the federally threatened California red-legged frog (*Rana aurora draytonii*).

Summary of ecotoxicological effects

100. Dicofol is highly toxic to aquatic animals ($NOEC_{fish}$ = 0.0044 mg/L) and can severely affect the reproduction in birds (e.g. eggshell thinning and feminization of male embryos). The acute toxicity values of the dicofol metabolites p,p'-DCBP and p,p'-FW-152 (96h-LC_{50fish} = >2.29 and 0.24 mg/L, respectively) are indicating for p,p'-FW-152 high toxicity to fish. Endocrine related effects have been observed in a broad range of tests with cells originating from different animal species as well as of human origin.

Adverse effects on human health

101. The toxicity of dicofol was assessed by WHO 1996, 2009, EPA 1998, IARC, 1998, the European Union in the frame of the assessment of active substances in plant protection products, 2006, JMPR, 2011. An acceptable daily intake (ADI) of 0.002 mg/kg has been derived (JMPR 2011). A chronic reference dose of 0.0004 mg/kg bw/day has been established by EPA (EPA, 1998). An acute reference dose of 0.15 mg/kg has been established by Spain, based on neurotoxicity in rats (Spain, 2006, EFSA, 2011). EPA established an acute reference dose of 005 mg/kg bw (EPA, 1998). Several toxicity studies on dicofol had been published before 1980, with a dicofol preparation with lower purity degree (below 95 % containing more than 0.1 % DDT relating impurities) and therefore may not be currently marketed any more (WHO, 1996). However, as depicted in section 2.1.1 this might not be true for all countries. The DDT contaminant could have been contributed to the effects seen in the older studies.

102. Classification and labelling: Dicofol is classified for its hazards to human health according to the Globally Harmonized System as acute toxic, category 4, H302 (harmful if swallowed) acute toxic, category 4, H332 (harmful if inhaled) skin irritant, category 2, H315 (causes skin irritation) and sensitising to skin, category 1, H 317 (may cause an allergic skin reaction) (EC 2015).

103. Metabolism and toxicokinetics are well described in WHO (1992), US EPA (1998) and JMPR (2011). Single doses of 25 mg/kg were administered to male mice. Approximately 60% of the administered dose was eliminated within 4 days primarily in the faeces. Faecal excretion accounted for 40% of the administered dose whereas urinary excretion accounted for 20%. Peak tissue concentrations were reached within 24-48 h. The highest concentrations of the radiolabelled compound were found in adipose tissue followed by liver, kidney, lung, heart, blood plasma, brain, whole blood, and spleen Concentrations dropped rapidly over 4 days except in adipose tissue (Kaneshima et al., 1980). Metabolism studies in rats were performed with radiolabelled dicofol, administration of high (50 mg/kg bw single treatment) and low (0.5 mg/kg bw for 16 days) doses were eliminated mainly with the faeces, and stored in adipose tissue. The metabolic pathways for dicofol were deduced, with the major one involving reductive halogenation to dichlorodicofol and oxidation to dichlorobenzophenone, dichlorobenzoic acid, and dichlorobenzil . The analysis of metabolites revealed at most 0.2% of the radioactive residue was DDE which could be contributed by the presence of DDT (0.2%) and DDE (0.01%) in the test material. The data indicated that dicofol metabolized differently from that of DDT, which is metabolized to the purported carcinogen, DDE (US EPA 1998).

104. Dietary feeding for 12 weeks (32 ppm) of rats had demonstrated, that after 8 weeks an equilibrium in fat (at 25 ppm for males and 70 ppm for females) was reached. After 12 weeks dicofol was withdrawn and concentrations declined, whereas in males it was zero after 14 weeks, but remained at about 6 ppm in females. Also higher and lower levels in the diet were stored to a higher extent in females than in males (IPCS, 1992).

105. Main adverse effects observed in short term dietary studies with laboratory rodents were on the liver, adrenals and the thyroid. The NOAEL in rats was 0.07 mg/kg bw/day and in mice 1.6 mg/kg bw/day. In dogs, target organs for dicofol toxicity were the adrenals, liver, heart and testes. The NOAEL was 0.29 mg/kg b.w./day. Cortisol response to ACTH was reduced; the LOAEL for these

effects (decrease in Cortisol release and oligospermatogenesis) was 3.3 mg/kg bw/day.(WHO, 1996). A 1-year dietary study in dogs (was reported with a NOAEL of 0.12/0.13 mg/kg bw/day (males/females) based on inhibition in ACTH stimulated cortisol release at 0.82 mg/kg bw/day. Dermal application in short term tests in rabbits (4 weeks/6 hours/day, 5 days/week) resulted in a NOAEL of 4 mg/kg bw/day (based on decrease in body weight) and in rats (13 weeks 6 hours/day, 5 days/week) of 4 mg/kg, based on liver hypertrophy (US EPA 1998).

106. Jadaramkunti et al. (2002) reported toxicity on testes and accessory reproductive organs in rats at doses of 400 mg/kg of a dicofol formulation administered by gavage for 30 days. Chan et al. (2009) examined the ability of dicofol to induce cytochrome P450 by treating 6-weeks old male Wistar rats with 1, 10 and 25 mg/kg dicofol intraperitoneally for four days performing histopathological evaluations, enzyme assays, gel electrophoresis and immunoblotting, reverse transcription-polymerase chain reaction (RT-PCR) analysis, and a sleeping time study (not conducted with 1 mg/kg bw). Thus, results of the study demonstrated that dicofol induces CYP1A1, CYP2B, CYP2E1 and CYP3A in rat liver and increases phenobarbital metabolism and CCl4 toxicity in rats at 10 and 25 mg/kg bw with a dose dependent increase.

107. The genotoxicity of dicofol was tested in a series of in vitro and in vivo tests. Negative results were obtained from gene mutation assays, however some limitations due to negative results of the positive control and the purity of the test substance were reported. Dicofol was also negative in in vitro and in vivo chromosome aberration and unscheduled DNA synthesis tests (WHO 1996, 2006). According to testing information of the NTP for dicofol, positive results in mouse lymphoma assays were found (IARC 1998; NTP 1978, 2015).

108. Dicofol was cytotoxic to human lymphoid cells at a concentration of 10^{-4} to 10^{-6} M (molar). In cultures incubated with 10^{-5} M dicofol, MI metaphases were as high as 13% compared to less than 1% in controls indicating an effect on cell cycle kinetics. Statistically significant increases in sister chromatid exchange frequency was seen in cells exposed to dicofol at 10^{-5} and 10^{-6} M (Sobti et al. 1983).

109. The European, US and IARC reports are in agreement that the dietary carcinogenicity studies performed with dicofol are negative in rats but positive in male mice at the highest dose (Spain, 2006, US EPA 1998, IARC, 1998). A bioassay for possible carcinogenicity carried out by the National Cancer Institute in the US reported statistically significant increases in hepatocellular carcinomas in dosed male mice, and the Institute concluded that dicofol was carcinogenic in male mice (NTP, 1978). Hepatocellular adenomas and carcinomas were observed at doses of 39.6 and 79.2 mg/kg bw/day treated for 45 weeks in males. No tumours were observed in females treated with 18.3 or 36.5 mg/kg/day (NTP 1978, US EPA 1998). This resulted so far in no EU GHS classification, an US group C, possible human carcinogen classification and an IARC conclusion that the available data are insufficient to evaluate the carcinogenicity of dicofol to humans.. From the long term study in rats a NOAEL of 5 ppm corresponding to 0.22 mg/kg bw/day was established on the basis of changes in liver and adrenal glands.

110. The reproductive toxicity was assessed in rats and rabbits. In a two generation reproduction study in rats a NOAEL of 0.4 mg/kg/day was established based on ovarian vacuolation in the F1 generation at 1.9/2.1 mg/kg/day in M/F; the NOAEL for offspring was 1.9 mg/kg bw/day based on reduced viability at 9.5/10.5 mg/kg bw M/F. The NOAEL for parental toxicity was 0.4 mg/kg/day; the LOAEL based on liver hypertrophy in both generations was 1.9/2.1 mg/kg/day in M/F. In a one generation postnatal toxicity study in rats a NOAEL of 1.7/2.0 mg/kg bw/day M/F for parents and offspring based on liver pathology seen at the LOAEL at 8.7/9.8 mg/kg bw/day M/F was derived. In a study in rabbits a NOAEL of 4 mg/kg bw/day for maternal and developmental toxicity was observed; the LOAEL was 40 mg/kg/day, based on an increased incidence of abortions in the does. A rat developmental toxicity study established a maternal NOAEL of 0.25 mg/kg bw/day, maternal effects were detected at 2.5 mg/kg bw/day whereas no developmental toxicity was observed at the highest dose of 25 mg/kg bw/day (US EPA, 1998). Toxic effects in offspring were not observed at maternal non-toxic doses, which would be indication for reprotoxicity. Exposure to dicofol at 2.5 mg/kg for eight weeks significantly reduced sperm motility in male Lewis rats. Sperm morphology, daily sperm production, sperm transit time through the epididymis, hormonal levels, and histopathological evaluation of testis and epididymis did not differ significantly. A mixture of dicofol and other pesticides at their NOEL also changed sperm motility (Perobelli et al. 2010).

111. Shahani et al. (2013) investigated the teratogenicity of the insecticide Colonel-S, a commercial formulation containing 18.5% dicofol in Swiss Albino mice. The insecticide formulation was orally administrated in a low and a high dose (resulting in a dicofol concentration of 4 and 16 mg/kg bw, respectively) to pregnant female mice during the entire organogenetic period of gestation (day 5-14).

Mice were sacrificed on day 18 of gestation for uteri examination for teratological changes. Treatment showed maternal toxicity (as evidenced by reduced maternal weight gain). A dose related decline in live litter size and rise in percentage of resorbed foetus was shown (low dose: 52.48% high dose 40.74%). In the high dose group, the percentage of alive foetuses was greatly reduced. However, mice from the low dose group did not exhibit significant alterations. The authors conclude that the tested formulation is a developmental toxicant in a dose-dependent manner.

112. Liu et al. (2012b) studied the interaction of dicofol with the globular protein trypsin in aqueous medium. Dicofol was shown to form spontaneously a complex with trypsin mainly by hydrogen bond with one binding site. The change in trypsin conformation was proved. The results indicated that dicofol had potential effects on structure as well as activity of trypsin and that the effects enhanced with increasing dicofol concentration. The results indicate that dicofol has deleterious effects on the frame conformation of proteins and disturbs their physiological function in vitro.

113. Liu et al. (2012a) examined the interaction between dicofol and serum protease α-chymotrypsin (α-CT) in aqueous medium. Three aspects including conformational change, interaction mechanisms and functional change were investigated. Dicofol bonded to α-CT and formed a stable complex unfolding the protein structure and increasing the exposure to chromophore groups in the internal hydrophobic region. Thus, dicofol exposure can lead to conformational changes of α-CT, which can lead to disturbed function and activities of enzymes. The effects enhanced with the increasing concentration of DCF.

114. A screen for nongenotoxic carcinogens identified dicofol as a compound that significantly stimulated phospholipid-dependent protein kinase C (PKC) in the absence of calcium. PKC plays a central role in the signal transduction pathway in cells, and thus is used as a potential marker that could be affected by carcinogens that act via non-genotoxic modes (Rotenberg, 1991). Dicofol was found to be a potent inhibitor of gap junction intercellular communication in in vitro assays (Flodström, 1990). According to the WHO dicofol was found to induce rat liver mixed function oxidase activity and ranked after heptachlor, DDT chlorfenson and dieldrin (WHO 1996).

115. Neurotoxicity was assessed in an acute and a subchronic study in rats. From the acute study a NOAEL of 15 mg/kg bw was established and the LOAEL was 75 mg/kg/.day (based on body weights and reduced food consumptions). At the highest dose observed, 350 mg/kg an increase in the incidence of ataxia and of uncoordinated landing was observed in females. From the subchronic study, the NOAEL was 0.3 mg/kg bw/day and the LOAEL was 5.6 mg/kg bw/day, based on decreased motor activity and increased liver weights. A significant decrease in brain weight was seen in males at 27.8 mg/kg bw/day (US EPA 1998).

Epidemiological studies

116. Settimi et al. (2003) investigated the association between different types of pesticides and prostate cancer in a case control study. They documented an increased risks among farmers exposed to organochlorine insecticides and acaricides (OR=2.5, 95% CI=1.4–4.2), more specifically to the often contemporary used compounds DDT (OR=2.1, 95% CI=1.2–3.8), and dicofol with tetradifon (OR=2.8, 95% CI=1.5–5.0), whose effects could not be well separated. . In general odds ratios (OR) of >1 generally mean that the respective exposure is associated with a higher odds of outcome. Until confirmed by other studies of prostate cancer in relation to past exposure to DDT and dicofol, the present results may be considered statistical artefacts arising from multiple comparisons. Nevertheless, these types of exposures could contribute to the excess of prostate cancer frequently reported among farmers, especially in view of some specific mechanisms of action reported for DDT.

117. Reynolds et al. (2005a) examined in a population-based case-control study early childhood cancer among California children aged 0-4 years who were born between 1990 and 1997 and the residential proximity to agricultural applications of pesticides of the mothers at the time of child birth. Two investigated pesticides were associated with a higher risk for leukaemia when comparing the highest and lowest categories including dicofol (OR: 1-49th percentile 0.75 (0.36–1.55 CI); ≥50th - percentile 1.83; 1.05-3.22 CI). Although they observed elevated risk for leukaemia in highest areas of use of dicofol, some limitations of the study were described; e.g. most children included in the study lived in areas with no or very low agricultural pesticide use; therefore the odds ratios for the highest exposure categories were based on small numbers.

118. Reynolds et al. (2005b) also evaluated in a case control study associations between rates of lympho proliferative malignancies among children from areas of intensive agricultural pesticide use in California, USA. Seven individual pesticides, ranked highest for toxicity and usage (dicofol among others) were separately analyzed. Among the investigated study population, children with Hodgkin's disease (n=258) were slightly elevated in areas with highest use of dicofol 1st-74th percentile OR: 0.77

(0.41–1.45 CI) versus ≥74th percentile OR: 1.43 (0.70–2.95 CI). The authors described limitations as well, e.g. the suitability of proximity as indicator of exposure and the small number of cases may have resulted in the association not being statistically significant.

119. Roberts et al. (2003) evaluated the hypothesis of the association between the maternal residence near agricultural pesticide applications during key periods of gestation and the development of autism spectrum disorders (ASD) in a case control study in children. Comparisons between children of mothers living within 500 meters of field sites with the highest nonzero quartile of organochloride use (endosulfan and dicofol) and children of mothers not living near field sites by multivariate a posteriori models suggested an Odds Ratio for ASD of 6.1 (95%CI 2.4-15.3). The risk for ASD increased with the percentage of organochlorine applied and decreased with increasing distance from field sites. Study authors noted this finding was not statistically significant and was based on a relatively small number of cases. Also it is noted that the RR was not increased for leukaemia. Although taking into account that the proportion of mothers living in proximity to pesticide applications during the defined time periods of interest was small in the study the possible connection between gestational exposure to dicofol and ASD gives reason for concern.

Neurotoxicity in humans

120. Several case reports on accidental exposure to dicofol describe effects of nausea, dizziness, weakness and vomiting. One case of poisoning of a 12 year old boy who was accidentally exposed to dicofol when he fell into a puddle of spilled undiluted dicofol formulation has been published. Initial symptoms were nausea, dizziness, disorientation, confusion, lethargy, and headache. The patient demonstrated horizontal nystagmus and impaired balance. These symptoms resolved within three weeks. Eight months after exposure impairment of certain cognitive functions including auditory attention, immediate memory, and ability to selectively inhibit inappropriate responses were shown (Lessenger and Riley 1991).

121. Mechanistic studies demonstrate that dicofol binds to gamma amino-butyric acid (GABA) receptor–mediated chloride ion channels in nerve cells (Sunol et al. 1998). GABA-mediated neurotransmission is expected to play important roles in gestational brain development.

Immunotoxicity

122. Ohnishi et al. (2008) investigated Kepone, a commercial formulation of dicofol in a study with a mouse macrophage cell line to evaluate the influence on innate immune function of macrophages. It could be demonstrated that lipopolysaccharide-induced activation of the interferon IFN-ß promoter was inhibited. This indicates that dicofol may influence the development of infectious diseases.

Endocrine Disruption

123. Dicofol has been identified as substance with at least some *in vitro* evidence of biological activity related to endocrine disruption (EC 2015). Effects on ovarian vacuolation have been detected at 2.1 mg/kg/day in a two generation study in rats (US EPA 1998). Endocrine disrupting effects have also been detected in a series of in vitro assays using different cell lines from various species. According to the WHO, endocrine disrupting effects are endocrine system related and not necessarily species dependent. Effects shown in wildlife or experimental animals may also occur in humans if they are exposed to EDCs at a vulnerable time and at concentrations leading to alterations of endocrine regulation. Of special concern are effects on early development of both humans and wildlife, as these effects are often irreversible and may not become evident until later in life (WHO 2012).

124. In their discussion of the need for a postnatal developmental neurotoxicity study with dicofol, EPA notes in their 1998 RED that "endocrine toxicity (adrenal and thyroid) was seen throughout the database". Dicofol was issued Tier 1 Endocrine Disruptor Screening Program (EDSP) test orders in 2009; however, the registrant ultimately opted to cancel the technical registration. The issuance of EDSP test orders was based on exposure potential and did not imply any conclusions regarding potential endocrine interaction (Annex E submissions, 2015, USA).

125. The OSPAR Commission listed dicofol as a potential endocrine disruptor in 1998. In 2002 it stated: "There is a lot of evidence of the toxic properties of dicofol and of its effects as an endocrine disrupter." The OSPAR Commission advised that the presence of dicofol in fresh water, even in very small quantities, for most of the growing season may have implications that there will be endocrine disruption of aquatic organisms.

126. One indication for endocrine disruption was a spill of KelthaneR (dicofol), which contained DDT at concentrations as high as 15%, and DDT's metabolites, DDD, DDE, and chloro-DDT into Lake Apopka, Florida. Studies at Lake Apopka spanned two decades, and identified a number of endocrine-disrupting effects on reproductive development in Lake Apopka alligators, in comparison to

the less contaminated reference site. Observations on alligators included a high mortality rate in embryos and neonates, and a higher ratio of oestradiol to testosterone in neonates which lead to histological differences in gonads. The effects seen could not be attributed to dicofol only but were rather mixture related (Guillette et al. 1994; US EPA 1998). A subsequent study on dicofol and other chemicals found in Lake Apopka determined that a mixture of DDT, DDT breakdown products, and dicofol reduced binding to alligator estrogen receptor by 40%. Dicofol alone reduced binding to alligator progesterone receptor by 40%, identifying potential routes by which dicofol, alone or in combination with other chemicals present in the lake, might elicit the endocrine-disrupting effects observed in Lake Apopka (Vonier et al. 1996).

127. Endocrine toxicity was seen also in rats and dogs; affecting the adrenals, the thyroid and ovaries (US EPA 1998; Jadarmkunti & Kaliwal, 1999). An increase of uterine weight in mice was reported by Zhao et al. (2000) as well as proliferation in the human breast cancer cell line MCF7 (Du & Xu, 2001).

128. In carp liver microsomes testosterone glucuronidation was significantly inhibited by dicofol (Lavado et al., 2004). Further it was shown that the synthesis of sex hormones in fish microsomes was influenced by dicofol (Thibaut & Porte 2004).

129. A series of in vitro studies with yeast or cell lines of different origin (e.g. human, hamster, alligator, frog, fish, chicken) have demonstrated that dicofol is able to bind to oestrogen receptors from various species and enhances transcriptional activity. The dicofol metabolite, DCBP showed potent antiandrogenic properties (Thiel et al. 2011). In a competitive binding assay p,p'-dicofol displaced up to 83% of 17 ß-estradiol from alligator estrogen receptor alpha (ERα) and was an equivocal binder to human ERα, displacing a maximum of 58% 17 ß-estradiol (Rider et al. 2010). Several studies have demonstrated that dicofol also interacts with the thyroid hormone receptor and related effects. Dicofol was a powerful inhibitor of the 3,5,3'--triiodothyronine (T3)-uptake system on the plasma membrane inhibiting more than 80% of the saturable initial uptake and significantly depressing the T3 response (Shimada & Yamauchi 2004). Dicofol exhibited a biphasic, nonmonotonic effect on thyroid hormone binding to transthyretins and inhibited T3 binding (Ishihara et al. 2003). It had strong T3- antagonist activity (Sugiyama et al. 2005) and exhibited relatively strong interference with the T4 binding site of transthyretin (van den Berg et al. 1991). An overview on endocrine related effects is provided in an information document to the risk profile.

Summary of adverse effects on human health

130. Dicofol is classified for its hazards to human health according to the Globally Harmonized System as acute toxic, category 4, H302 (harmful if swallowed) acute toxic, category 4, H332 (harmful if inhaled), skin irritant, category 2, H315 (causes skin irritation) and sensitising to skin, category 1, H 317 (may cause an allergic skin reaction). Target organs in short term toxicity tests were the liver, adrenals, the thyroid, heart and testes and the nervous system. Tumours have been observed in male mice at higher dose levels (39.6 and 79.2 mg/kg bw/day) but this finding did not lead to a GHS classification for carcinogenicity. Dicofol is classified as an US group C, possible human carcinogen and an IARC conclusion that the available data are insufficient to evaluate the carcinogenicity of dicofol to humans. Reprotoxic and developmental effects were observed at maternal toxic doses. A NOAEL of 0.3 mg/kg bw has been established based on neurotoxic effects observed in subchronic studies leading to an ADI of 0.002 mg/kg derived by JMPR. The NOAEL of 0.12 mg/kg in dogs based on inhibition of adrenal cortical trophic hormone stimulated release of cortisol in both sexes of dogs was used to establish a chronic reference dose of 0.0004 mg/kg bw/day from US-EPA. In vitro assays demonstrate interference with e.g. confirmation and function of proteins, inhibition of gap junction intercellular communication and immune reactions. Several epidemiological studies have noted associations between dicofol exposure and prostate cancer in men and leukemia, Hodgkins disease and autism disorders in children. Although limitations of these studies hinder causal associations they illustrate the concern that adverse effects associated with dicofol exposure might also occur in humans. Further mixture toxicity of dicofol and other organochlorine compounds may be of concern.

3. Synthesis of information

131. The estimated global dicofol usage decreased from 3,350 t in 2000 to 730 t in 2012. In total 28,200 t dicofol were estimated to be consumed worldwide during this period. Asia was the biggest consumer, accounting for 76.8% (21,700 t). China, by far the largest consumer during this period (19,500 t), showed a reduction of about 75% in its annual domestic usage from 2000 to 2012. In India, the annual dicofol consumption decreased from 145 t to 45 t during this period. An Indian state-owned enterprise still manufactures dicofol with an average annual production output of approximately 50 t.

There is evidence that, although dicofol is being produced in closed systems, improper production practices can result in direct release of DDT to the environment, as can DDT contamination in dicofol, especially if it is above the 0.1% threshold limit. Ongoing dicofol production and usage, and incineration of production waste, can be sources of PCDD/Fs contamination (see section 2.1.3)

132. O,p'-dicofol and p,p'-dicofol hydrolyze relatively quickly at neutral and alkaline pH's as shown by experimental data. However, both isomers are stable under acidic conditions. Hydrolytic stability at pH 5 under laboratory condition does not necessarily imply persistence because susceptibility to biodegradation by microorganisms in environmental media may occur. However, fast hydrolysis rates cannot alone lead to conclude that a substance is not persistent according to ECHA (2014).

133. Photodegradation is not expected to be a significant route of dissipation of dicofol in the environment. Dicofol is not readily biodegradable. Dicofol degrades rapidly in water/sediment systems with a pH >7. No data for water/sediment systems at pH<7 were reported. Experimental evidence suggests that abiotic as well as biotic degradation are dependant on the pH value of the receiving environmental compartment with longer degradation half-lives under acidic conditions. Several laboratory studies reported low mineralisation of dicofol. In laboratory soil simulation tests high DT50 values >180 days (n=3) have been reported for some soils, however also degradation half-lives of 8.5 and 32 days for o,p'- and p,p'-dicofol indicate that dicofol is not expected to persist in soils. Field trials conducted in Florida and California indicated a range of dissipation half-lives of a few days up to 72 days with one reported value of 113 days, depending upon the specific environmental conditions. Based on the physical chemical data the volatilisation and leaching potential of dicofol is considered to be low. No field studies from other locations or colder climates are available.

134. A conservative estimate for persistence of p,p'-dicofol and major degradates of as high as 313 days versus 32 days for the parent compound alone in soil (pH 7.8) was reported by a regulatory body. The UN ECE Task Force on POPs concluded that dicofol is persistent in water at a pH of 5 or below and meets the persistency indicative numerical value of EB decision 1998/2 (UN ECE, 2009). Aquatic ecosystems with acidic water are black water rivers, 14% (pH ≤6), and 3% (pH ≤5) of lakes and rivers in Northern Europe. It can be anticipated that dicofol and/or its degradation products will persist longer in these ecosystems. Recent monitoring data have shown that dicofol is sufficiently persistent to be transported via riverine input to the open sea and one study has measured dicofol in remote regions. Modelled data indicate that the persistence of dicofol in the environment is lower or comparable to benchmark substances and known POPs.

135. The reported log Kow values for dicofol range between 3.5 and 6.6. Based on a screening approach for bioaccumulation potential, a log Kow range of 3.5 to 6.06 and a log Koa range of 8.9 to 10.02, indicates a high bioaccumulation potential of dicofol in both air-breathing organisms and aquatic organisms.

136. In three laboratory BCF studies with bluegill sunfish and common carp, BCF values are 6,100, 8,200 and 10,000 (steady-state calculated BCF of 25,000). Metabolism of dicofol was minimal in bluegill sunfish with an estimated elimination half-life of 33 days. In a full life cycle test the highest observed BCF value was 43,000. Experimental evidence of high bioaccumulation (BCF of 10,000) in invertebrates during 28 days of exposure was shown. Based on experimental studies in fish species dicofol has a high bioaccumulation potential (BCF >5,000). Model predictions for dicofol also suggest biomagnification in terrestrial species; although metabolic transformation was not taken into consideration. Recent monitoring data in heron eggs showed elevated levels compared to prey items, however values were not lipid corrected and therefore no conclusion on biomagnification can be made.

137. If released to air, a vapour pressure and the partitioning coefficients indicate that dicofol will exist in both the vapour and particulate phases in the atmosphere. Atmospheric oxidation by hydroxyl radicals is a possible removal pathway for dicofol in the atmosphere with half-lives of 3.1 to 4.7 days. Model results concerning LRT for dicofol depend on the model used. Whereas the MSC East indicated a lower travel distance and environmental persistence than the benchmark chemical Benzo[a]pyrene, the OECD Pov and LRT tool indicated a characteristic travel distance and transfer efficiency comparable to already identified POPs. The most recent modelling assessment showed that the Arctic contamination potential of dicofol is comparable to known POPs; dicofol can be transported to remote regions with moderate efficacy but results in high calculated enrichment in the Arctic environment. Though monitoring information from remote regions for dicofol is limited, transport via air (mainly in the gas phase but also on airborne particle) and seawater to the high Arctic has been demonstrated in one study. No measurements from biota in remote regions were available. It should be noted that for chlordecone, a substance listed in the Stockholm Convention, the assessment for LRT was based on physical-chemical properties and modelling data (UNEP/POPS/POPRC.2-17 Add.2).

138. Degradation products are considered in the hazard profile of dicofol. This is common practice in the UNEP POP assessment. Major degradates of dicofol with a higher persistence than dicofol include DCBP, FW-152, DCBH, OH-DCBP and DCBA. DCBP, FW-152 and DCBH accumulated in a water/sediment study and can be considered as persistent in sediment. Modelled log K_{OW} values for the metabolites are below the screening value of 5 but according to high log Koa values high bioaccumulation in terrestrial organisms may occur (no metabolism is considered). The estimated bioaccumulation potential for the metabolite FW-152 indicated a BCF >5,000 for fish. The acute LC50 toxicity values of p,p'-DCBP and p,p'-FW-152 for rainbow trout are >2.29 and 0.24 mg/L, the later indicating high toxicity to fish. The metabolite p,p'-DCBP has been shown to reveal potent antiandrogen activity *in vitro*.

139. Dicofol is classified according to the Globally Harmonized System as hazardous for the aquatic environment: aquatic acute H400 (very toxic to aquatic life) and aquatic chronic H410 (very toxic to aquatic life with long lasting effects). The acute toxicity values of dicofol, p,p'-DCBP, and p,p'-FW-152 for rainbow trout (96h-LC50) are 0.053, >2.29 and 0.24 mg/L. The lowest chronic effect concentration of dicofol (95d-NOEC) for fish is 0.0044 mg/L. Among terrestrial species dicofol has a NOAEC for chronic effects in birds and a NOAEL in mammals of 1 mg/kg and 0.4 mg/kg bw/day, respectively.

140. Dicofol has been detected in environmental compartments like seawater, surface waters, air, sediment and soil and in a variety of biota, including fish, molluscs, cattle and birds. But as there are analytical difficulties in the detection of dicofol (e.g. thermal breakdown during analysis, degradation to DCBP and the inability of differentiation from other DCBP sources if only DCBP is detected and degradation at high pH) and these problems may have not been sufficiently addressed, results have to be regarded with caution. In several studies dicofol is indirectly detected via the ratio of o,p'-/p,p'-DDT, but especially in areas with no dicofol use and remote areas, the use of isomer ratios for the estimation of their emission source has to be utilized cautiously.

141. Dicofol levels in biota in crop areas have been reported for small mammals (up to 1.4 mg/kg), terrestrial invertebrates (up to 3.9 mg/kg) and reptiles/amphibians (up to 3.8 mg/kg). In non-crop areas detected values were in earthworms (up to 2 mg/kg), fish (0.26 mg/kg), birds (0.9 mg/kg) and in eggs (annual mean: 0.03-0.46 mg/kg). The detected dicofol levels in fish are well above the laboratory derived acute and chronic effect levels. On a local scale, the environmental concentrations in water bodies in areas of dicofol use (0.0036 mg/L) are in the range of the chronic effect level in fish (NOEC, 0.0044 mg/L). The detected concentrations in birds and mammals are in the range of observed chronic effect concentrations, which may indicate the potential for adverse effects in wildlife caused by the observed environmental concentrations in biota in crop areas. According to US EPA (2009) risk assessment of dicofol use, risks to aquatic invertebrates, fish, aquatic-phase amphibians, terrestrial-phase amphibians and mammals were identified.

142. The available data demonstrate interactions with the endocrine system in a multitude of different tests and test systems. Findings from animal experiments show also adverse effects in endocrine organs and hormonal imbalances. Mixtures of pesticides including dicofol at their NOAEL and LOAEL administered to rats via the diet lead to impairment of sperm motility and effects on the estrous cycle, hormone levels, and number of developing ovarian follicles. Evidence for mixture toxicity has also been derived from an accidental spill of KelthaneR (a dicofol formulation, which contained DDT at concentrations as high as 15%, and DDT's metabolites, DDD, DDE, and chloro-DDT) leading to histological differences in gonads and a high mortality rate in embryos and neonates of alligators at the contaminated lake. A dramatic decline in the alligator population has been observed in the years after the spill. Therefore mixture toxicity of dicofol, ΣDDT and other organochlorines might be a cause of concern for humans and wildlife.

143. Subchronic and chronic toxicity studies of dicofol lead to toxic effects in target organs (liver, thyroid, adrenals, brain, heart, testes) of mammals at low concentrations (NOAEL 0.22 mg/kg). Neurotoxicity has been demonstrated in acute and subchronic studies. A series of mechanistic in vitro studies on endocrine disruption, enzyme induction intercellular communication, signal transduction and protein binding support evidence for adverse effects, which may lead to tumour promotion. Risk assessment for consumers clearly demonstrates exceedances of ADIs. Several epidemiological studies have noted associations between dicofol exposure and prostate cancer in men and leukemia, Hodgkins disease and autism disorders in children. Although limitations of these studies hinder causal associations they illustrate the concern that adverse effects associated with dicofol exposure might also occur in humans. Further mixture toxicity of dicofol, ΣDDT and other organochlorines is a cause of concern for human and wildlife.

4. Concluding statement

144. Dicofol is restricted or prohibited in many countries and generally usage as a pesticide has markedly decreased in the last decade and was below 1,000 tonnes in 2012.

145. [Dicofol can be atmospherically transported to areas far from local sources, including Arctic and subarctic regions]. Dicofol and its transformation products are persistent in the environment and fulfil the persistency criterion of Annex D (under acidic conditions). Dicofol fulfils the bioaccumulation criterion of Annex D based on high BCF values in aquatic species.

146. Dicofol is highly toxic to the aquatic environment and toxic for reproduction in birds. Dicofol has been shown to be neurotoxic in mammals; it further affects the thyroid, the liver and the adrenals. There is evidence suggesting the relevance of adverse effects on humans. Endocrine related effects were reported in a series of in vitro assays. Indications from animal experiments showing adverse effects in endocrine organs, reproductive development and hormonal imbalances. A risk assessment based on exposure scenarios in various countries clearly demonstrates a risk for consumers (up to 1379% of ADI). Further the toxicity of mixtures of dicofol, DDT and other organochlorines is a cause of concern for humans and wildlife.

147. [Based on its inherent properties and taking into consideration the toxicity of mixtures of organochlorine compounds, dicofol as a result of its long-range environmental transport, is likely to lead to significant adverse human health and environmental effects, such that global action is warranted.]

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